

REDACTED DOCUMENTS RELATED TO DOCKET 7946

7946 - Plaintiffs' Controverting Statement of Facts in Opposition to Bard's Motion for Partial Summary Judgement as to Debra Mulkey

REDACTED EXHIBITS:

- Exhibit A: Selected Medical Records of Debra Mulkey;**
- Exhibit B: Expert Report of Darren Hurst, M.D.;**
- Exhibit C: Excerpts of 4/11/17 Deposition of [REDACTED], M.D.;**
- Exhibit D: Excerpts of 2/8/17 Deposition of Debra Mulkey; and**
- Exhibit E: Debra Mulkey Fact Sheet**

**REDACTED DOCUMENTS
RELATED TO DOCKET 7946**

**EXHIBIT A
FILED REDACTED**

200 240 280 320 360 400 440 480 520 560 600 640 680 720 760 800 840 880 920 960 1000

1000

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Patient Name:
Account Class:
Attending Physician:

Service	Cost	Rev.	Proc.	Description	Qty.	Amount
Date	Ctr.	Code	Code			

Hospital Charges

Total hospital charges:

Payments

2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	2101	2102	2103	2104	2105	2106	2107	2108	2109	2110	2111	2112	2113	2114	2115	2116	2117	2118	2119	2120	2121	2122	2123	2124	2125	2126	2127	2128	2129	2130	2131	2132	2133	2134	2135	2136	2137	2138	2139	2140	2141	2142	2143	2144	2145	2146	2147	2148	2149	2150	2151	2152	2153	2154	2155	2156	2157	2158	2159	2160	2161	2162	2163	2164	2165	2166	2167	2168	2169	2170	2171	2172	2173	2174	2175	2176	2177	2178	2179	2180	2181	2182	2183	2184	2185	2186	2187	2188	2189	2190	2191	2192	2193	2194	2195	2196	2197	2198	2199	2200	2201	2202	2203	2204	2205	2206	2207	2208	2209	2210	2211	2212	2213	2214	2215	2216	2217	2218	2219	2220	2221	2222	2223	2224	2225	2226	2227	2228	2229	2230	2231	2232	2233	2234	2235	2236	2237	2238	2239	2240	2241	2242	2243	2244	2245	2246	2247	2248	2249	2250	2251	2252	2253	2254	2255	2256	2257	2258	2259	2260	2261	2262	2263	2264	2265	2266	2267	2268	2269	2270	2271	2272	2273	2274	2275	2276	2277	2278	2279	2280	2281	2282	2283	2284	2285	2286	2287	2288	2289	2290	2291	2292	2293	2294	2295	2296	2297	2298	2299	2300	2301	2302	2303	2304	2305	2306	2307	2308	2309	2310	2311	2312	2313	2314	2315	2316	2317	2318	2319	2320	2321	2322	2323	2324	2325	2326	2327	2328	2329	2330	2331	2332	2333	2334	2335	2336	2337	2338	2339	2340	2341	2342	2343	2344	2345	2346	2347	2348	2349	2350	2351	2352	2353	2354	2355	2356	2357	2358	2359	2360	2361	2362	2363	2364	2365	2366	2367	2368	2369	2370	2371	2372	2373	2374	2375	2376	2377	2378	2379	2380	2381	2382	2383	2384	2385	2386	2387	2388	2389	2390	2391	2392	2393	2394	2395	2396	2397	2398	2399	2400	2401	2402	2403	2404	2405	2406	2407	2408	2409	2410	2411	2412	2413	2414	2415	2416	2417	2418	2419	2420	2421	2422	2423	2424	2425	2426	2427	2428	2429	2430	2431	2432	2433	2434	2435	2436	2437	2438	2439	2440	2441	2442	2443	2444	2445	2446	2447	2448	2449	2450	2451	2452	2453
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**REDACTED DOCUMENTS
RELATED TO DOCKET 7946**

**EXHIBIT B
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Expert Report

Debra Mulkey v. CR Bard Inc.

Darren R. Hurst, M. D.

Director Vascular and Interventional Radiology

Department of Radiology

[REDACTED]

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1. My name is Darren R. Hurst. I am a full time physician and fellowship trained vascular and interventional radiologist. The discipline of vascular and interventional radiology involves the diagnosis, treatment and management of medical diseases and health conditions through imaging and targeted, image-guided, minimally invasive surgical procedures. The procedures I perform involve the introduction of medical devices into the human body under image guidance such as ultrasound, CT, and fluoroscopy. Often, this involves the use of needles, guidewires, catheters, balloons, stents, drains, and other medical devices. My education, training, and experience are detailed in my CV which is in appendix A of this report. My practice is located in Edgewood, Kentucky, and serves the Greater Cincinnati, Ohio area. I am familiar with the issues, subject matter, and topics involved in this litigation. I have personal experience with the use of both permanent and retrievable inferior vena cava filters for the prevention of pulmonary embolism. As part of my practice, I regularly implant and retrieve inferior vena cava filters. I am familiar with the relevant medical literature that addresses the issues concerning IVC filters, including, but not limited to, the indications and contraindications for use, placement, complications, and risks and benefits of the devices. I am also familiar with and have utilized multiple different types of filter devices including the Bard Simon Nitinol Filter®, Recovery Filter®, G2 Filter®, G2X Filter®, Eclipse® and Denali Filter®. This experience, in combination with my education and training in the field of medicine, and specifically, the field of Vascular and Interventional Radiology, has formed the basis for my opinions rendered in this litigation.

2. Case Specific Materials Reviewed

a. Medical Records:

i. [REDACTED]

- vi. Dr. [REDACTED] 2/2/12 – 5/23/13
- vii. Dr. [REDACTED] 11/11/13 – 2/23/17

b. Imaging Reviewed:

[REDACTED]

c. Depositions:

- i. Debra Mulkey 2/8/17.
- ii. [REDACTED], M. D. 4/11/17.
- iii. [REDACTED], M.D. 3/28/17.
- iv. Scott Karch 3/20/17

d. IFU

- i. Bard Eclipse and Meridian Filters.

e. Bard Documents and Depositions (See Appendix)

f. Expert Reports

- i. Drs. Kinney, Roberts, and Kalva
- ii. Mark Eisenberg, M. D.
- iii. I have reviewed these reports, I agree with them, and I adopt the opinions and bases for those opinions set forth therein.

3. Case Summary:

a. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

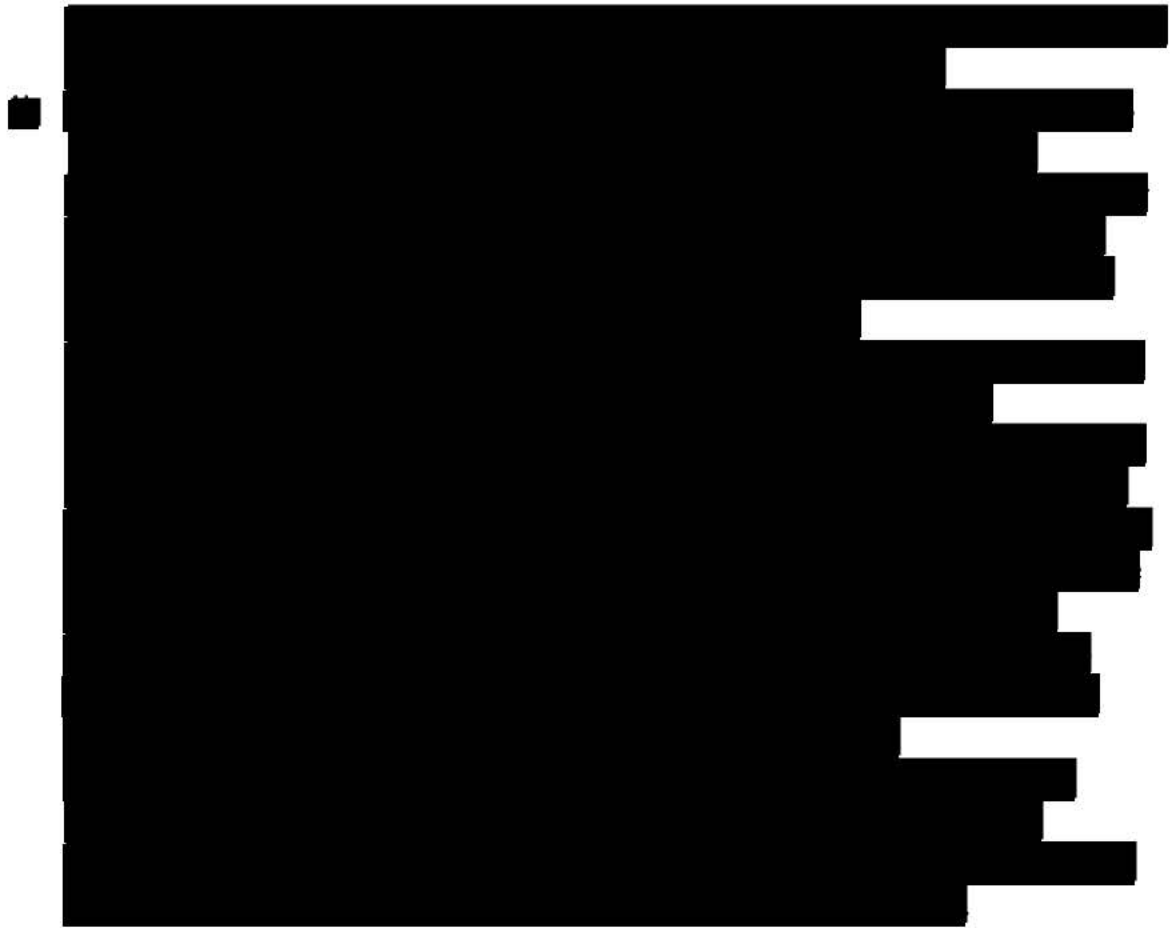
[REDACTED]

[REDACTED]

4. Opinions:

a. Summary of clinical events:

- i. [REDACTED]
[REDACTED] As discussed above, the



- b. Reasonable expectations of physicians for medical devices:
- i. In the everyday practice of medicine, I along with my colleagues/implanting and treating physicians have expectations of medical device companies like CR Bard and Bard Peripheral Vascular (referred to collectively in this report as “Bard”) when they design, manufacture, market, and sell medical devices. Fulfilling these expectations in their design, testing, manufacturing, warning, and marketing of IVC Filters allows physicians to properly and completely obtain informed consent from their patients. Fulfillment of these expectations also allows physicians to select the appropriate IVC filter and make appropriate therapeutic decisions on behalf of their patients whether an IVC filter is indicated or considered as a therapeutic option, and whether to use or not use a particular type of IVC filter.
 - ii. Moreover, a patient has reasonable expectations on what he/she should know in the same or similar circumstances as a reasonable patient who has been prescribed or has considered having an IVC filter implanted.

c. Informed Consent:

- i. The AMA Code of Medical Ethics - CHAPTER 2: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING, 2.1.1 *Informed Consent* states: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should: (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about: (i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

<https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics- chapter-2.pdf>.

- ii. The AMA Code of Medical Ethics' Opinion 8.08 – Informed Consent states: The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the

patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information (see Opinion 8.122, "Withholding Information from Patients").

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

<http://journalofethics.ama-assn.org/2012/07/coet1-1207.html>.

I have adopted the above AMA Codes in my daily practice and, in my opinion, they represent the standard of care relative to Informed Consent, Patient Communication and Decision Making.

d. Failure to notify:

- i. Given the above responsibilities of the medical device manufacturer to the patient and the physician, and the physician to the patient, it is my opinion that Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery®, G2®, and Eclipse® filters in comparison to the original predicate device, the Simon Nitinol Filter®, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality and performance. (Example: G2 Brochure: "...strength and stability to a new level.")
- ii. There were multiple early safety signals with the Recovery®, G2®, and Eclipse® filters. These signals came from adverse event reports/sales data, from reports in the medical literature, from Bard's internal risk analysis, and from Bard's own in vitro testing indicating low migration resistance compared to other filters, and in some instances failing to meet Bard's arbitrary minimum threshold for migration

resistance under a variety of foreseeable circumstances. For example, Bard's own internal risk analysis deemed the G2 filter [REDACTED] other than electropolishing) to pose an "unacceptable risk" of caudal migration.

iii. [REDACTED]

[REDACTED] Bard continued to market the device for both permanent and retrievable indications in the prevention of PE from DVT. During this time, Bard acknowledged design flaws that needed to be corrected, but instead chose to inappropriately utilize the data from the Grassi paper, and ignore their in house studies, risk analysis and the current medical literature, to justify the high complication rates and continued marketing practices. In essence, Bard chose to keep the product on the market until a new product was released rather than focusing on its duty to remove unsafe devices from the market.

iv. At the time [REDACTED]

[REDACTED] Bard's next generation filter, the Meridian, was already being marketed and sold – having been launched in August of 2011. Among other changes, the Meridian filter was the first Bard filter to add caudal anchors for the purpose of "improving caudal migration resistance and tilt performance." As Bard was aware, the Eclipse filter (identical to the G2 and G2X filters with exception of electropolishing) suffered from a significant increased safety risk of caudal migration (a risk which Bard internally deemed "unacceptable") over competitor filters, and even earlier Bard filters (including the Simon Nitinol). Bard was also aware at that time that caudal migration leads to tilt, perforation/penetration, complicated or high risk retrievals and fracture. All of this was despite Bard initiating an internal project to correct caudal migration of the G2 filter beginning in February of 2006, a fact that was not passed on to physicians or patients, and making no changes to address those caudal migration problems until launch of the Meridian in August of 2011 – more than 5 years later. Moreover, despite awareness of the need to correct the caudal migration problem with its filters, Bard launched the G2X and Eclipse, filters to which no changes were made to address the caudal migration safety risk, prior to launching the Meridian. Despite all of this, Bard continued selling the Eclipse filter [REDACTED]

██████████ did not remove those filters from medical facilities, and did nothing to communicate to physicians and patients that the Meridian should be used in lieu of the Eclipse. In my opinion, Bard should have never launched the Eclipse without the safety design changes required by the unacceptable risk of caudal migration the company knew existed with the G2 by late 2005/early 2006. Having made that choice to launch the Eclipse without these important patient safety design changes, Bard should have stopped selling the Eclipse and removed it from all medical facilities at the time it launched the Meridian filter. ██████████

- v. In addition, Bard's marketing materials falsely represented newer generation devices as having greatly improved strength and stability when many of the changes in the devices from generation to generation were minimal and unproven in their impact on safety and efficacy.
- vi. Bard elected not to perform studies to further evaluate the safety, effectiveness and durability of their filters. Instead, they embarked on a long term plan to evolve their filter through multiple generations while making small incremental changes to each generation in response to the safety issues that were arising in real time in patients that were unknowingly participating in a decade long open experiment with Bard retrievable filters.
- vii. Had I been ██████████
██████████ I would not have used Bard filters for the prevention of PE in my patients. I would have also advised my partners and colleagues to do the same. It is my opinion that Bard did not adequately warn physicians, including ██████████ implanting physician, of important safety risks and issues associated with its filters of which it was aware. The implanting physician in this case, ██████████, M. D., seems to agree based on his deposition testimony. As one example, he testified "I wouldn't use the filter if I was aware that deaths were occurring concurrently with me placing these filters". (Mulkey Deposition pg. 53, lines 21-23).

e.

i.

Bard

represented the Eclipse® IVC filter as a device that could be safely placed temporarily, provide effective protection from PE, and then be easily removed percutaneously. Given this backdrop, I render the following opinions:

1.

2.

filter has failed to perform as a reasonable physician and/or patient would expect in that it has tilted, caudally migrated, perforated her vena cava, interacted with and perforated surrounding vital organs and structures, a piece of the filter has fractured, and the filter cannot be removed via a simple percutaneous procedure as intended. This filter currently affords no benefit to [REDACTED] and only exposes her to ongoing risks that include, without limitation, further tilt of the filter, further perforation of the vena cava, further interactions with and penetration of adjacent vital organs and structures, further fracture of the filter, further caudal migration of the filter, increased risk of thrombosis, and the development of DVT, PE, caval thrombosis, and filter occlusion.

3. Because the filter could not be removed using the standard techniques and equipment recommended by Bard, [REDACTED]

[REDACTED] Due to the significant risks and potential complications associated with open, surgical removal of the Eclipse Filter, it is reasonable

for removal of this filter to first be attempted via advanced, complex percutaneous techniques. If this retrieval is unsuccessful, surgical removal will be necessary. Both procedures have many risks which include, without limitation, IVC perforation, bleeding, filter fracture, filter migration, IVC thrombosis, IVC stenosis, infection, and morbidity and mortality.


4. [REDACTED]
5. [REDACTED]
6. [REDACTED]
7. Because of the above symptoms, and additional risk of fracture, migration or increased penetration, the filter cannot remain as a permanent filter as falsely marketed and represented to myself and other physicians by Bard. Based on my experience, review of the available literature, and Bard internal documents, Bard retrievable filters lack the durability to remain implanted permanently despite being marketed and represented by Bard to physicians as safe for permanent use.

[REDACTED]

More specifically, the device lacks adequate migration resistance, strength and stability. I reviewed Ms. Mulkey's medical records and imaging, and performed a differential diagnosis in reaching this

opinion, and there are no other reasonable causes of the failures of her Eclipse Filter.

- f. My opinions are based on the reasonable expectations I and other similarly situated physicians have in regards to the responsibilities of a medical device manufacturer in regard to the design, marketing, sales, and performance of their medical devices.
- g. My opinions are based on my review of scientific and medical literature, the materials and medical records/films in this case, Bard internal documents, depositions, expert reports, and my clinical experience, education and training. I did my own medical literature research and review, as well as reviewing literature provided to me by the plaintiff's counsel.
- h. In rendering my opinions in this matter, I took into consideration [REDACTED] medical history and preexisting problems.
- i. All of my opinions are to a reasonable degree of medical and scientific certainty.
- j. I understand that discovery is ongoing in this case. There may be additional information in the form of medical literature, expert reports, depositions, and case material. I reserve the right to amend my opinions if further pertinent information is discovered/obtained.



Darren R. Hurst, M. D.

June 5, 2017

APPENDIX

Bard Materials and Depositions Reviewed:

1. Janet Hudnall Email to David Rauch dated 2/26/04
2. Natalie Wong Email to Doug Uelmen dated 5/20/04 and attachment
3. Natalie Wong Email to Doug Uelmen dated 5/27/04
4. Health Hazard Evaluation from David Ciavarella dated 12/17/04
5. G2 Perforations from Christopher Ganser dated 11/10/05
6. G2 Caudal Migrations from David Ciavarella dated 12/27/05
7. G2 Filter System - indicated for retrieval
8. G2 Filter System - Patient Questions & Answers
9. SWOT - Objective: Increase Revenue and Capture More Market Share
10. Monthly Global PV Report from John McDermott dated 2/10/06
11. Health Hazard Evaluation from David Ciavarella dated 2/15/06
12. G2 Caudal Migration Update dated 3/2/06
13. G2 Fracture Report November 2008
14. G2 and G2X Fracture Analysis dated 11/30/08
15. BARD IVC Filter Program May 2009 – Mike Randall
16. Letter from Stacy Taiber to Brent Adamson, M.D.
17. Filter Naming Memo from Bill Little dated 4/27/10
18. Eclipse 510(k) sections on changes to filter from predicate

19. Eclipse Product Performance Specification for Migration from Design History File
20. Meridian Product Performance Specification for Caudal Migration from Design History File
21. Meridian Value Proposition from Design History File
22. Meridian Commercialization Plan dated 10/1/10
23. G2 Platinum PowerPoint
24. Scott Karch Email to Dr. Thomas dated 3/6/12
25. Brian Barry Deposition - 1/31/14
26. Robert Michael Carr, Jr. Deposition - 4/17/13
27. Robert Michael Carr, Jr. Deposition - 10/29/14
28. Robert Michael Carr, Jr. Deposition - 11/5/13
29. Clement J. Grassi, M.D. Deposition - 7/30/14
30. Clement J. Grassi, M.D. Deposition - 8/27/14
31. Clement J. Grassi, M.D. Deposition - 9/24/14
32. Murray Asch, M.D. Deposition - 5/2/16
33. Kay Fuller Deposition - 1/11/16
34. David Ciavarella, M.D. Deposition - 11/12/13
35. Christopher Ganser Deposition - 10/11/16
36. Janet Hudnall Deposition - 11/1/13
37. John Mcdermott Deposition - 2/5/14
38. Gin Shultz Deposition - 1/30/14

- 39. Douglas Uelmen Deposition – 10/4/14
- 40. Carol Vierling Deposition – 5/11/16
- 41. Natalie Wong Deposition – 10/18/16
- 42. Steven Williamson Deposition – 9/7/16
- 43. Medical Monitoring 30(b)(6) Deposition (John Van Vleet) – 1/17/17

Literature Reviewed:

MEDICAL ARTICLES	
TITLE	AUTHOR(S)
Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study	Binkert
In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters	Bjarnason
Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters	Cantwell
Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Caplin
Complications Encountered with the Use of the Greenfield Filter	Carabasi
Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma Patients	Carlin
Update on Vena Cava Filters	Carman
G2 Inferior Vena Cava Filter: Retrievability and Safety	Charles
Prophylactic Inferior Vena Cava Filters: Do They Make a Difference in Trauma Patients? (abstract only)	Cherry
Complications of vena cava filters: A comprehensive clinical review	Cipolla

TrapEase Inferior Vena Cava Filter Placed via the Basilic Arm Vein: A New Antecubital Access	Davison
Removal of Fractured Inferior Cava Filters: Feasibility and Outcomes	Dinglasan
Celect Inferior Vena Cava Wall Strut Perforation Begets Additional Strut Perforation	Dowell
Perforation of the IVC: Rule Rather Than Exception After Longer Indwelling Times for the Gunther Tulip and Celect Retrievable Filters	Durack
"Reporting the Impact of Inferior Vena Cava Perforation By Filters" JOURNAL OF VASCULAR SURGERY; Vol. 55, No. 1	Wood
PRESERVE Study to be a Comprehensive Evaluation of Inferior Vena Cava Filter use	Endovascular Today
Clinical Experience with the Antecubital Simon Nitinol IVC Filter	Engmann
Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use	FDA
Percutaneous Inferior Vena Caval Filters: Follow up of Seven Designs in 320 Patients	Ferris
Medical Literature and Vena Cava Filters	Girard
Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Grassi
Vena Caval Occlusion after Simon Nitinol Filter Placement: Identification with MR Imaging in Patients with Malignancy	Grassi
Long-Term Follow-up of the Antheor Inferior Vena Cava Filter	Harries
Retrieval of the Recovery Filters after Arm Perforation, Fracture, and Migration to the Right Ventricle	Hull
Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration	Hull
Single Institution Prospective Evaluation of the Over-the-Wire Greenfield Vena Caval Filter	Johnson
Vena Cava Filter Fracture: Unplanned Obsolescence	Johnson

Decision Analysis of retrievable inferior vena cava filters in patients without pulmonary embolism	Morales
Recovery Vena Cava Filter: Experience in 96 Patients	Kalva
Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: an AAST Multicenter Study	Karmy-Jones
Guidelines for the Use of Optional (Retrievable and Convertible) Vena Cava Filters	Kaufman
Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference	Kaufman
Development of a Research Agenda for Inferior Vena Cava Filters: Proceedings from a Multidisciplinary Research Consensus Panel	Kaufman
Update on Inferior Vena Cava Filters	Kinney
High Risk Retrieval of Adherent IVC Filters: Techniques and Management of Thrombotic Complications	Kuo
High-Risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications	Kuo
Modified Loop Snare Technique for the Removal of Bard Recovery, G2, G2 Express, and Eclipse Inferior Vena Cava Filters	Lynch
Removal of the G2 filter: differences between implantation times greater and less than 180 days	Lynch
Complications of the Nitinol Vena Caval Filter	McCowan
Indications for Vena Cava Filters for Recurrent DVT	Miller
Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters	Millward
Improving Inferior Vena Cava Filter Retrieval Rates: Impact of a Dedicated Inferior Vena Cava Filter Clinic	Minocha
Realistic expectations and candidate selection for entry level vascular technologist in a busy laboratory	Mutyala

Letter to the Editor: A Complication of a G2 Bard Filter	Nazzal
Complications Related to Inferior Vena Cava Filters: A Single-Center Experience	Nazzal
Long-term Follow-up of the Bird's Nest IVC Filter	Nicholson
Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade	Nicholson
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Correction to Article About Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters	Nicholson
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Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval	Oliva
Recovery G2 vena cava filter retrievability study	Oliva
Intracardiac Migration of Inferior Vena Cava Filters	Owens
Long-term Results of the Simon Nitinol Inferior Vena Cava Filter	Poletti
Aortic Pseudoaneurysm after Penetration by a Simon Nitinol Inferior Vena Cava Filter	Putterman
Complications of Inferior Vena Cava Filters	Ray
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Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience	Simon
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Embedded Inferior Vena Cava Filter Removal: Use of Endobronchial Forceps	Stavropoulos
Complications of Vascular Access Procedures in Patients with Vena Cava Filters	Streib

Fracture and Distant Migration of the Card Recovery® Filter: A retrospective Review of 363 Implantations for Potentially Life-Threatening Complications	Tam
Vena Tech Vena Cava Filter: Experience and Early Follow-Up	Taylor
Management of Severe Vena Cava Filter Tilting: Experience with Bard G-2 Filters	Turba
FDA Safety Communication: Removing Retrievable Inferior Vena Cava Filters	U.S. Food and Drug Administration
Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts	Vijay
Retrievability and Device-Related Complications of the G2® Filter: A Retrospective Study of 139 Filter Retrievals	Zhu
Data Desert for Inferior Vena Caval Filters: Limited Evidence, Supervision, and Research	Bikdeli
Inferior vena cava filters	Duffett and Carrier
Vena Cava Filter Use in Trauma and Rates of Pulmonary Embolism, 2003-2015	Cook

Curriculum Vitae:

Darren R. Hurst, M. D.

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Education:

Fellowship in Vascular and Interventional Radiology
University of Michigan Medical Center
1999-2000

Residency in Diagnostic Radiology
University of Michigan Medical Center
Dept. Award for Research Excellence 1999
1995-1999

Doctor of Medicine
University of Cincinnati College of Medicine
AOA Honor Society 1994-95
1991-95

B. A. in Zoology
Miami University, Oxford, Ohio
Cum Laude with University Honors
1987-91

Employment Experience:

Radiology Associates of Northern Kentucky
Managing partner
Regional multispecialty radiology and imaging group
2001-Present

Director Vascular & Interventional Associates
Division of Radiology Associates of NKY
Private practice VIR group
2003-Present

Director VIA Vein Center

Comprehensive Vein Center
2013-Present

Chief of Vascular & Interventional Radiology
St. Elizabeth Health System
2003-Present

Director IR Spine Intervention
St. Elizabeth Spine Center
St. Elizabeth Health
2009-2016

Physician Trainer for Spine Intervention
Stryker International
2011-2015

Hospital Affiliations:

St. Elizabeth Health
Edgewood Campus
1 Medical Village Drive
Edgewood, Kentucky 41017
859-344-2000

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Covington Campus
401 East 20th Street
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Private Practice Office:

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Certification: ABR Certified in General Diagnostic Radiology 1999

ABR CAQ Board Certification
Vascular and Interventional Radiology 2001

ABR MOC/CAQ 10yr Recertification
Vascular and Interventional Radiology 2011

Kentucky License #35686
Ohio License #4536
Indiana License #010682666A

Professional Organizations:

RSNA: 1995
ARRS: 1995
ACR: 1998
SIS: 2010
SIR: 1999
ACP: 2015

Publications:

Hurst DR, Forauer AR, Bloom JR et al: Diagnosis and Endovascular Treatment of Iliocaval Compression Syndrome. *J Vasc Surg* 34(1):106-13, 2001.

Hurst DR, Kazerooni EA, Williams DM, Stafford-Johnson D, Platt JF, Prince MR: Diagnosis of Pulmonary Embolism: Comparison of MR Angiography and CT Angiography in Canines. *JVIR* 10:309-318, 1999.

Dong Q, **Hurst DR**, Wienmann HJ, Chenevert TL, Londy FJ, Prince MR: Magnetic Resonance Angiography With Gadomer-17: An Animal Study Original Investigation. *Investigative Radiology* 33:699-708, 1998.

Donnelly LF, **Hurst DR**, Strife JL, Shapiro RM: Plain Film Assessment of Pulmonary Flow in the Neonate with D-Transposition of the Great Vessels. *Pediatric Radiology* 25:195-7, 1995.

Research:

VOYAGER PAD Study: An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures. Lead Investigator St. Elizabeth Health System 2014-present.

ATTRACT Study: a multicenter randomized trial to evaluate pharmacomechanical catheter-directed thrombolysis for the prevention of postthrombotic syndrome in patients with proximal deep vein thrombosis. Lead Investigator St. Elizabeth Health System 2013-present.

The CAPTURE registry: analysis of strokes resulting from carotid artery stenting in the post approval setting: timing, location, severity, and type. Co-investigator St. Elizabeth Health System 2005-2007.

The Fibroid Registry for outcomes data (FIBROID) for uterine embolization. Lead Investigator St. Elizabeth Health System 2001-2005.

Testimony List:

1. Susan Gail Smith v. St. Mary's Medical Center et al. 8/11/2015
2. Barbara Bongiorno v. Phillip Adler M. D.; St. John Macomb Hospital
1/21/2016
3. James Alley v. Hillcrest Medical Center et al. 3/15/16
4. Edith Fish v. Diallo et al. 11/7/2016
5. Austin v. CR Bard Inc. 8/19/16
6. Austin v. CR Bard Inc. 11/16/16

Fee Schedule:

1. My current fee for the following medical legal activities is \$500.00 per hour. This includes medical records review, review of depositions, literature searches, consultation time, preparation for deposition and trial testimony, oral or written reports, all travel time (billed as portal to portal), or any miscellaneous task as requested by client.
2. My current fee for all local deposition and trial activities is \$750.00 per hour.
3. All out of area travel that requires an overnight stay is billed at \$6000.00 per day. If I have to use a half day for travel or return from the location of trial or deposition, that will be billed at 3000.00 per half day. If I must cancel an entire office day to provide the requested services, an additional fee of \$2000.00 per clinic/work day will be charged. Trial and out of area fees must be paid in advance of the date of travel.

**REDACTED DOCUMENTS
RELATED TO DOCKET 7946**

**EXHIBIT C
FILED REDACTED**

Do Not Disclose - Subject to Further Confidentiality Review

1 UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA
2 No. MD-15-02641-PHX-DGC
3

4 In Re: Bard IVC Filters Products
Liability Litigation
5

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6 CONFIDENTIALITY REVIEW

7
WITNESS: [REDACTED], M.D.

8
9 Pursuant to Fed. R. Civ. P. 26 and 30
10 the videotaped deposition of Roderick Tompkins,
11 M.D. was taken before Janine N. Leroux,
12 Stenographic Court Reporter and Notary Public -
13 Special Commission in and for the State of
14 Kentucky at Large, at the 613 23rd Street, Suite
15 440, Ashland, Kentucky on Tuesday, April 11,
16 2017, commencing at the approximate hour of 4:45
17 p.m. Said deposition was taken pursuant to
18 Notice.
19
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1 be -- I will be doing the same thing on my
2 objections.

3 BY MR. DeGREEFF:

4 Q Has anyone from Bard ever made you
5 aware of deaths caused by the Bard IVC filters?

6 A No.

7 Q If there were deaths caused by Bard IVC
8 filters that you were using in patients, is that
9 something you'd want to know?

10 MS. HELM: Object to the form.

11 A Yes.

12 Q It would be important for you to know,
13 right?

14 A Yes.

15 Q Something you would consider in making
16 your decisions about which filter to use?

17 MS. HELM: Object to the form.

18 A If it -- yes.

19 Q And is that something that you would
20 pass on to your patients?

21 A I wouldn't use the filter if I was
22 aware that deaths were occurring concurrently with
23 me placing these filters.

24 Q Okay. Are you aware that -- that
25 perforation is progressive in nature?

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1 accounts, yes.

2 MS. HELM: Object to the form.

3 A And so what was the question?

4 Q I'll withdraw it.

5 We were talking earlier about sales
6 representatives being present when you were doing
7 IVC placements in bariatric patients. Do you
8 remember that?

9 A Yes.

10 Q Did you ever have any specific
11 discussions with those reps about the use of IVC
12 filters in bariatric patients?

13 A I don't recall.

14 Q Okay. Do you remember ever being told
15 by any Bard sales representative that IVC filters
16 should not be used in bariatric patients?

17 A No.

18 Q Would you expect the -- the information
19 that a -- that a medical device sales rep was --
20 was providing to you to be honest, accurate and
21 complete?

22 A Yes.

23 Q And would the same be true of a medical
24 device company in general?

25 A Yes.

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1 product?

2 A Yes.

3 Q And something that you would use when
4 meeting with patients?

5 A Yes.

6 Q If there were problems with one of
7 Bard's IVC filters such as the Eclipse for
8 example, would you have expected the Bard sales
9 rep to inform you of those problems?

10 MS. HELM: Object to the form.

11 A Yes.

12 Q And were you ever told by any Bard
13 sales representative about problems with the
14 Eclipse filter?

15 MS. HELM: Object to the form.

16 A No.

17 Q Were you ever told by any Bard sales
18 representative about any -- any problems or
19 complications associated with any of their
20 filters?

21 MS. HELM: Object to the form.

22 A No.

23 Q Sir, let's go through some of your
24 records, and I'm going to try to -- I tried to
25 find the earliest I could find.

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1 possible IVC filter insertion prior to
2 laparoscopic gastric bypass due to limited
3 mobility."

4 Did I read that correctly?

5 A Yes.

6 Q And why did you believe -- at this
7 point were you recognize -- were you actually
8 talking about putting in a filter, or were you
9 just talking about the possibility of an IVC
10 filter?

11 A Possibility of placing a filter.

12

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22 Q So the limited mobility would have been
23 the basis for the potential hyper-coagulative
24 state?

25 A Yes.

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1 sentence says, "The proximal duodenum was normal,"
2 correct?

3 A Yes.

4 Q And what is the proximal duodenum?

5 A There's four parts to the duodenum.

6 The proximal duodenum is the first part.

7 Q Okay. Am I saying it correct or wrong
8 when I say duodenum?

9 A It depends on what country you're from.

10 Q Okay. What country says is that way?

11 A England.

12 Q So how should I be saying it?

13 A Duodenum.

14 Q That's what I used to say but then --

15 MR. O'CONNOR: I told you.

16 Q -- everybody else said duodenum. So I
17 should go with duodenum?

18 A In America it's normally duodenum.

19 Q Perfect. I am definitely from America.

20 All right. So looking at Page 13, this

21 appears to be a [REDACTED] operative report
22 from a [REDACTED]; is that correct?

23 A Yes.

24 Q And what was the purpose of this

25 [REDACTED]?

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1 Bates No. 19 is again [REDACTED], right?

2 A Yes.

3 Q And then [REDACTED]: [REDACTED]

4 [REDACTED] correct?

5 A Yes.

6 Q [REDACTED]

7 [REDACTED]?

8 MS. HELM: Object to the form.

9 A [REDACTED]

10 [REDACTED]

11 Q [REDACTED]

12 [REDACTED]

13 A [REDACTED]

14 Q [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 I guess did I read that first sentence
20 correctly?

21 A Yes.

22 Q [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

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[REDACTED]

Do you remember in particular what was
discussed with [REDACTED]

[REDACTED]

A What's typed right there.

Q Okay. And what would you have told [REDACTED]

[REDACTED]

A What is right there.

Q Let -- let me ask you when you're
talking about [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

A [REDACTED].

Q [REDACTED]?

A Yes.

Q Okay. [REDACTED]

[REDACTED] Would -- [REDACTED]

[REDACTED]

A Yes.

[REDACTED]

A Perforation of the filter?

Q All right. Well --

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1 MS. HELM: Object to the form.

2 Q Yeah, that's a -- fair enough.

3

4

5 A Not past insertion.

6 Q Okay. So you would have been talking
7 about surgical only?

8 A Yes.

9 Q And what -- and what about -- and then
10 you -- and then you

11

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17 Q Okay. S

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20 A Yes.

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25 A Yes.

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MS. HELM: Object to the form.

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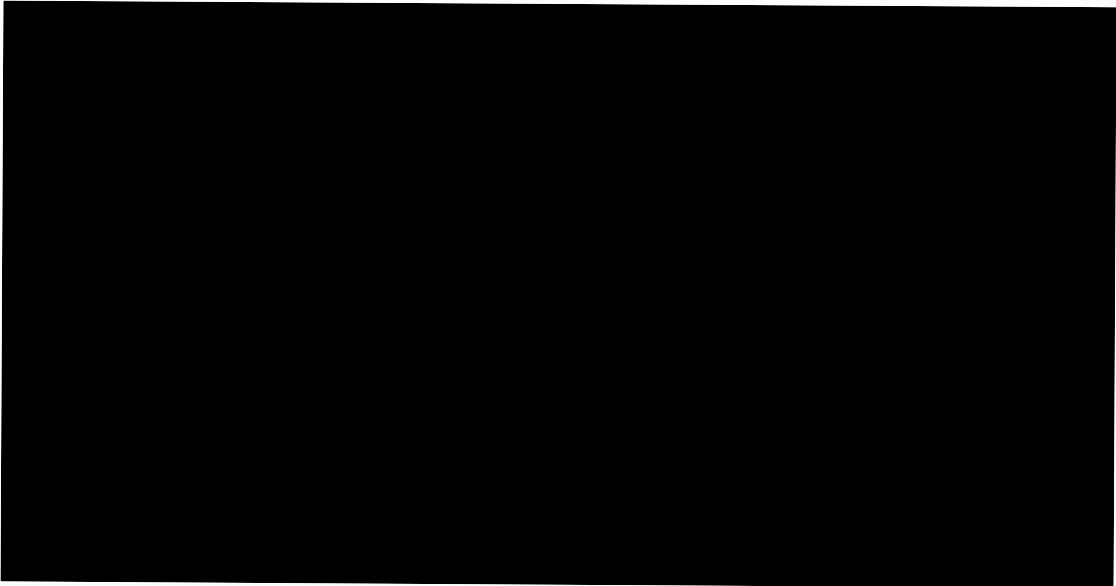
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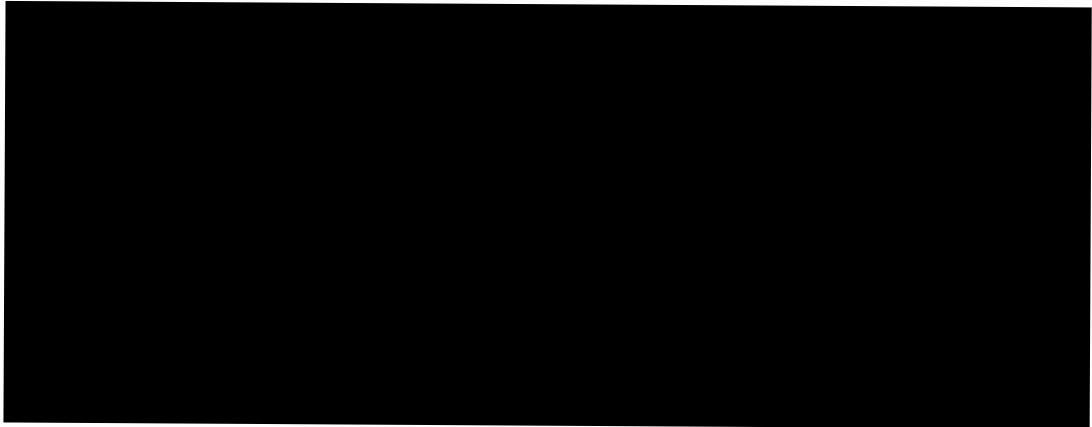
A In what's documented here, yes.

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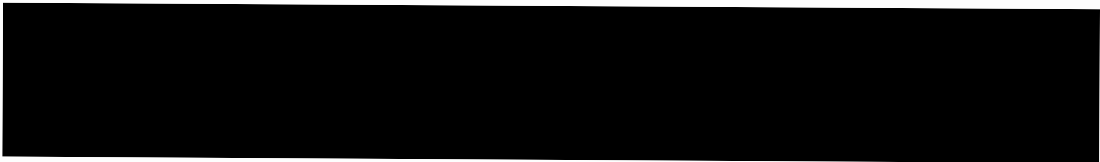
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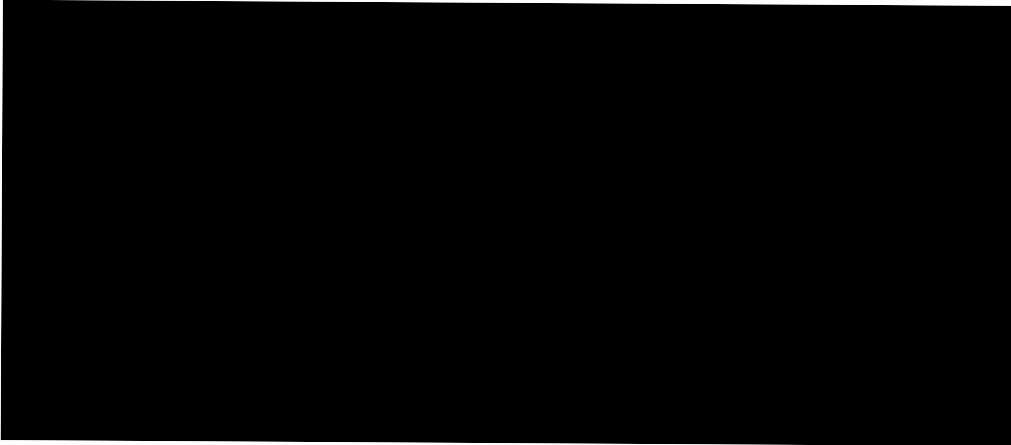
MS. HELM: Object to the form.



MS. HELM: Object to the form.



MS. HELM: Object to the form.



Do Not Disclose - Subject to Further Confidentiality Review

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MS. HELM: Object to the form.

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MS. HELM: Object to the --

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Q -- is that correct?

14

MS. HELM: Object to the form.

15

A In our discussion here, no. I assume

16

you have the consent form in here somewhere.

17

Q I do. And we'll -- we'll talk about

18

that.

19

But isn't the -- would the consent form

20

essentially have the same -- is it essentially a

21

statement of --

22

A Yes.

23

MS. HELM: Object to the form.

24

Q Would there be things in the consent

25

form that would be different than what you've

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1 listed here?

2 A No.

3

4

5

6

7

8 A What is there, an FDA statement had
9 come out shortly prior to this that we began to
10 inform the patients that the FDA said it should be
11 removed.

12 Q Are you talking about the July 2010 FDA
13 statement?

14 A Are there others?

15 Q (Laughter). Do you remember
16 specifically when they --

17 A No.

18 Q Okay. And what did the FDA say about
19 removal of IVC filters?

20 A They should be retrieved if possible.

21 Q And why?

22 MS. HELM: Object to the form.

23 A I don't recall.

24 Q Was it your intention and expectation
25 that the IVC filter you were going to place into

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1 And so this was a record from
2 April 11th of 2012; is that correct?

3 A Yes.

4 MS. HELM: Exactly five days ago today.

5 MR. DeGREEFF: Hey, you were married
6 exactly --

7 MS. HELM: 25 years ago today.

8 MR. DeGREEFF: That's right. Happy
9 anniversary by the way.

10 MS. HELM: Where is my bottle of
11 champagne?

12 MR. DeGREEFF: I know who would you
13 rather be with?

14 MS. HELM: On the advice of counsel I
15 decline to answer.

16 MR. DeGREEFF: There you go. All
17 right. I'm sure I'm super high on that list.

18 BY MR. DeGREEFF:

19 Q So -- so in -- in deciding which --
20 which filter to use, do you rely on information
21 from the manufacturer?

22 A No.

23

24

25 A That's what I'm looking for.

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1 A Okay.

2 Q All right. You state that the risks --
3 under indications and findings it says, "The risks
4 and benefits were discussed with the patient and
5 consent was obtained."

6 Did I read that correctly?

7 A Yes.

8 Q And is that -- would you have told her
9 anything other than what we have already
10 discussed?

11 A No.

12 Q And is this -- is this consent that was
13 obtained, is that a reference to the consent
14 document?

15 A Yes.

16 MR. DeGREEFF: 9?

17 COURT REPORTER: Yes.

18 MR. DeGREEFF: Thank you, ma'am.

19 (DEPOSITION EXHIBIT 9 WAS MARKED.)

20 BY MR. DeGREEFF:

21 Q I'm handing you what's been marked as
22 Deposition Exhibit 9. So does that appear to be
23 the consent --

24

25 A Yes.

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1 Q And if you'll look at the -- and this
2 is a consent -- this is titled 'Consent to
3 Operation or Other Procedures', correct?

4 A Yes.

5 Q So is this a consent to the
6 complications -- potential complications
7 associated with the -- with the actual procedure
8 for implantation?

9 A Yes.

10

11

12

13 A Yes.

14 Q And then the paragraph under that says,
15 "Some of the common additional risks particular to
16 this surgery is/are", and then it lists,
17 "malfunction/dysfunction of filter, blood vessel
18 injury." Did I read that correctly?

19 A Yes.

20 Q And again, is that the same
21 information that -- or strike that.

22 Would there be anything different about
23 this than what we discussed earlier with regard to
24 your consent discussion with her?

25 A No.

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1 inspected the filter and delivery system for any
2 damage prior to implanting it?

3 A I would have looked at it, yes.

4 Q Okay. You wouldn't have -- I guess
5 strike that.

6 Would you have implanted it if there
7 was any indication of damage or a problem with the
8 filter?

9 A No.

10 Q And you didn't -- did you do anything
11 to alter or change the filter before implantation?

12 A No.

13 Q Is it fair to say that you -- strike
14 that.

15 Did you just open the package and make
16 sure it wasn't damaged and go ahead and implant
17 it?

18 MS. HELM: Object to the form.

19 A Yes.

20 Q At the time you implanted the filter,
21 did you expect the filter to perform properly?

22 MS. HELM: Object to the form.

23

24

25 Q Okay. Did you -- did you expect the

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1 filter to tilt and become irretrievable at the
2 time that you placed it?

3 A No.

4 MS. HELM: Object to the form.

5

6

7 MS. HELM: Object to the form.

8 A I'm not aware of that. Or did I expect
9 it to perforate? Read that back.

10

11

12 MS. HELM: Object to the form.

13

14

15 Q No, okay, strike that. No, that's not
16 what I meant.

17

18

19

20 A No.

21 MS. HELM: Object to the form.

22

23

24

25 A No.

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1 Q Would you -- if you expected those --
2 those issues to occur, would you have used the
3 filter?

4 MS. HELM: Object to the form.

5 A No.

6 Q And is it -- in your opinion is it
7 reasonable for a patient to expect those
8 complications not to occur?

9 MS. HELM: Object to the form.

10 A Unfortunately there's complications
11 with any product.

12 Q Well, if -- if a patient is not
13 informed of those complications, they can't
14 reasonably make a decision whether -- strike that.
15 Move on.

16 The IVC filter complications can occur
17 even if -- even if the implanting physician does
18 everything correctly; is that correct?

19 MS. HELM: Object to the form.

20 A Yes.

21 Q Doctor, would you agree that a -- that
22 a perforation of the vena cava filter is -- is not
23 within a patient's reasonable expectations?

24 MS. HELM: Object to the form.

25 A The perforation of the vena cava

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1 Q Strike that. Let me see if I can say
2 that a better way.

3 Is it reasonable for a -- for a patient
4 to expect a vena cava filter not to penetrate its
5 -- their vena cava?

6 MS. HELM: Object to the form.

7 A It's reasonable that they wouldn't
8 expect that, yes.

9 Q Okay. And would it -- is it reasonable
10 for a patient to expect an IVC filter not to
11 penetrate their organs?

12 MS. HELM: Object to the form.

13 A That is what they should expect.

14 Q In your -- and in your experience would
15 it be a rare and unusual circumstance where a vena
16 cava filter would perforate a patient's organs?

17 MS. HELM: Object to the form.

18 A Yes.

19 Q That's not something that you would
20 expect to occur, correct?

21 MS. HELM: Object to the form.

22 A It's certainly within the realm of
23 small risks.

24 Q Is it -- when you're putting a filter
25 into a patient, that's not something you would

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1 expect to occur; is that fair?

2 MS. HELM: Object to the form.

3 A It's something that can occur, but it's
4 not something I would expect to occur.

5 Q Okay. Doctor, what is -- that would
6 not be within your reasonable expectation of an
7 outcome from a -- from a future implantation -- of
8 a future outcome from an implanted IVC filter,
9 fair?

10 MS. HELM: Object to the form.

11 A It would be a possible but not likely
12 outcome.

13 Q Okay. Doctor, are you -- do you know
14 what an IFU is?

15 A I have heard but I've forgotten.

16 Q Are you familiar with the instructions
17 for use for vena cava filters?

18 A Yes.

19 (DEPOSITION EXHIBIT 10 WAS MARKED.)

20 Q I'm handing you what's been marked as
21 Exhibit 10. Have you seen the instructions for
22 use for the Eclipse filter before?

23 A Yes.

24 MS. HELM: Are you representing that
25 this is the IFU filter at issue?

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1 to be contraindicated for something?

2 A Those are the situations in which it's
3 not advisable to place it.

4 Q If a -- if a -- if something was listed
5 as a contraindication for use in the IFU, would
6 you implant the filter in -- in those situations?

7 A No.

8 Q Contraindications for use does not
9 include bariatric surgery, does it?

10 A No.

11 Q If -- if contraindications for use in
12 the Eclipse IFU had listed bariatric surgery,
13 would you use the filter in bariatric patients?

14 A No.

15 Q Do you review the IFU for medical
16 devices that you use?

17 A I have seen this. I don't know that
18 I've read every word in it.

19 Q Okay. Is it your practice, though, to
20 review the IFU for devices that you're implanting
21 into your patients?

22 A If it's a new device, I would look it
23 over.

24 Q And is -- and part of the reason you
25 review an IFU is so that you can properly inform

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1 patients; is that correct?

2 MS. HELM: Object to the form.

3 A No.

4 Q You wouldn't -- you wouldn't inform
5 patients of warnings that are listed in an IFU?

6 A If they were pertinent.

7 Q Okay. If the IFU included pertinent
8 warnings, is that something that you would pass on
9 to your patients?

10 A Yes.

11 Q I want you to look at the -- at the
12 warnings section. If you look on it's Page 881.
13 12 says, "Movement" --

14 A Which 12, the upper?

15 Q The upper --

16 A The top 12?

17 Q The upper 12, sorry, under the warnings
18 sections it says, "Movement, migration or tilt of
19 the filter are known complications of vena cava
20 filters.

21 Migration of the filters to the heart
22 or lungs has been reported. There have also been
23 reports of the caudal migration of the filter."

24 Did I read that correctly?

25 A Yes.

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1 Q This section -- strike that.

2 Does this make any differentiation
3 between Bard filters and competitor filters?

4 A I don't know.

5 Q Would you read it to make any
6 differentiation between Bard filters and
7 competitor filters?

8 MS. HELM: Object to the form.

9 A Would I read what?

10 Q The language we just talked about.
11 "Movement, migration or tilt of the filter are
12 known complications of vena cava filters."

13 That's discussing all vena cava
14 filters, correct?

15 MS. HELM: Object to the form.

16 A That's how I would read it, yes.

17 Q Is there anything about that statement
18 that informs you of an increased risk of movement,
19 migration or tilt with Bard filters versus
20 competitor filters?

21 A No.

22 Q Is there anything about that statement
23 that warns you of an increased risk of movement,
24 migration or tilt with Bard filters versus -- Bard
25 optional filters versus Bard's permanent filters?

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1 MS. HELM: Object to the form.

2 A No.

3 Q There's -- is there anything that would
4 -- about that language that would lead you as a
5 physician to believe that the Eclipse had a higher
6 risk of movement, migration or tilt than any other
7 filter?

8 MS. HELM: Object to the form.

9 A No.

10 Q If the -- if the Bard filter, the
11 Eclipse, had an increased risk of migration over
12 other filters, is that something you would want to
13 know?

14 MS. HELM: Object to the form.

15 A Yes.

16 Q Is that something you would take into
17 account in your risk benefit analysis on whether
18 to use the filter?

19 A Yes.

20 Q Would it effect your prescribing
21 habits?

22 A Yes.

23 Q Is it something you would pass on to
24 the patient?

25 A If it's a significant difference, I

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1 wouldn't use the filter.

2 Q Doctor, as a -- as a physician, would
3 you want to use the safest available IVC filter
4 that would establish the goal of stopping PEs?

5 MS. HELM: Object to the form.

6 A Yes.

7 Q And, Doctor, just below that there's
8 a -- in bold it says, "See potential complications
9 section for further information regarding other
10 known filter complications."

11 Did I read that correctly?

12 A I don't see that.

13 Q It's the bold right below No. 14.

14 MS. HELM: My copy is so bad you can't
15 tell that it's bolded.

16 A Yeah, I don't know that it's bold.
17 Yeah, I see what you're saying.

18 Q And it says, "See potential
19 complications section for" -- and for the record
20 this is how it was produced to us, so there's not
21 a lot we can do about it.

22 And it says, "See potential
23 complications for further information regarding
24 other known filters complications."

25 Did I read that correctly?

Do Not Disclose - Subject to Further Confidentiality Review

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A Yes.

4

5

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Q Okay. And when a -- when a filter

11

becomes embedded and irretrievable, the patient

12

continues to have the risk of tilt -- I mean the

13

risk of perforation of the filter, correct?

14

MS. HELM: Object to the form.

15

A I'm not an expert on the long-term

16

consequences of filters.

17

Q Okay. So as you sit here, you're not

18

-- you're not -- you don't consider yourself an

19

expert on any long-term complications of filters?

20

A No.

21

Q Okay. Have you spoken to the

22

interventional radiologist who tried to remove the

23

filter?

24

A Not that I'm aware of.

25

MR. DeGREEFF: Go ahead. No, wait. I

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1 penetration of the IVC filter into the duodenum
2 could cause chronic abdominal pain?

3 MS. HELM: Object to the form.

4 A Perforated intraluminally into the
5 duodenum?

6 Q Yes.

7 A Potentially.

8 Q What about tenderness of the abdomen?

9 A If the vena cava filter were visible
10 within the lumen of the duodenum, then it may
11 cause some ulceration.

12 Q Which would leave the tenderness of the
13 abdomen?

14 A Yes.

15 Q And what about abdominal cramping?

16 A Yes.

17 Q What about nausea?

18 A Well, your -- yes.

19

20

21 A No.

22

23

24

25 A No.

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A No.

4

MR. DeGREEFF: Go ahead.

5

DIRECT EXAMINATION

6

BY MR. O'CONNOR:

7

Q All right. Doctor, I'm Mark O'Connor

8

and I'm another lawyer representing the Plaintiff

9

in this matter. I have some additional questions.

10

I've sat here and listened to you and

11

it sounds to me as though you are a medical doctor

12

who places your patients' interest and safety and

13

their well-being as a No. 1 priority; is that

14

fair?

15

MS. HELM: Object to the form.

16

A That and having a outcome, yes.

17

Q And is it fair to say, Doctor, that you

18

would expect that a medical device manufacturer

19

would similarly place a patient's interest and

20

safety first as a priority when it is promoting a

21

medical device?

22

MS. HELM: Object to the form.

23

A Sometimes there are risks to devices

24

but...

25

Q As a general rule, though, is it your

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1 I'm not a marketing expert. I don't know --

2 Q Setting marketing aside, if Bard was
3 aware that there were rates of complications
4 stemming from caudal migration in the Eclipse
5 filter, I think we've agreed that that's something
6 you would have expected them to tell you?

7 MS. HELM: Object to the form.

8 A Yes.

9 Q And told you as soon they knew, right?

10 MS. HELM: Object to the form.

11 A As soon as they verified there was a
12 significant issue.

13 Q And if they were receiving feedback
14 from other doctors that there were problems in the
15 Eclipse with caudal migration as early as 2010, is
16 that something you also would have expect to
17 notify you as a doctor who was using the Eclipse?

18 MS. HELM: Object to the form.

19 A I -- I wouldn't expect that from A
20 marketing standpoint. I would assume they would
21 improve the filter.

22 Q Well, you would expect Bard to provide
23 you with accurate and through information as it
24 became aware of problems with the filter, right?

25 A Yes.

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1 A Yes.

2 Q If Bard was aware that there were
3 problems with the designs of a filter that was on
4 the market that was causing complications and
5 problems with patients, would you expect Bard to
6 notify you about that immediately?

7 MS. HELM: Object to the form.

8 A Yes.

9 Q And would you expect Bard to notify you
10 immediately if it was in the process of
11 redesigning the filter in a manner to reduce or
12 avoid the complications?

13 MS. HELM: Object to the form.

14 A Yes.

15 Q Because that information would help you
16 decide whether you even wanted to use the filter
17 in the first place, true?

18 A Yes.

19 MS. HELM: Object to the form.

20 Q Did you have an understanding, Doctor,
21 you -- you had the Eclipse filter. Did you have
22 an understanding that there were filters that were
23 launched by Bard that were predecessors to the
24 Eclipse filter?

25 A Was I aware there were predecessors?

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1 complications because of her physical condition,
2 correct?

3 A Yes.

4

5

6

7 A Yes.

8 Q Okay. And so that was part of your
9 risk-benefit analysis?

10 A Yes.

11 Q Okay. If you would turn the page of
12 this IFU, which marked I've as Exhibit 17, and on
13 the next page under G you see where it says,
14 "Potential complications"?

15 A Yes.

16 Q And it says, "Possible complications
17 include but are not limited to the following." Do
18 you see where I am?

19 A Yes.

20 Q And again -- again they tell you
21 "Movement, migration or tilt the filter are known
22 complications of vena cava filters," correct?

23 A Yes.

24 Q And they also tell you that "Migration
25 of filters to the heart or lungs have been

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1 intervention."

2 Did I read that correctly?

3 A Yes.

4 Q [REDACTED]

5 [REDACTED] Bard told you -- had
6 told you that there had -- that complications
7 could result in medical intervention and/or death,
8 correct?

9 A They provided me with this literature.

10 Q Yes, they provided you with
11 information.

12 A Yes.

13 Q And they told you that there had been
14 reports of complications including death
15 associated with the use of IVC filters in morbidly
16 patients, correct?

17 A They provided me with literature that
18 stated that, yes.

19 Q Yes, okay. And they provided you with
20 literature that stated you needed to take that
21 into consideration when doing your risk-benefit
22 analysis in deciding whether to implant a filter

23 [REDACTED]

24 A Yes.

25 Q Okay. And this information was

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1 available to you when you made that risk-benefit
2 analysis?

3 A Yes.

4 Q Okay. Today you were shown a number of
5 internal documents from Bard. Do you recall
6 those?

7 A Yes.

8 Q Some e-mails and some other internal
9 documents. Do you recall those?

10 A Yes.

11 Q During the course of your practice, has
12 any medical device company ever shown you their
13 internal documents?

14 A No.

15 Q During the course of your practice, has
16 any internal -- any medical device company ever
17 shown you a draft e-mail?

18 A No.

19 Q Okay. It is important to you to have
20 reliable information when making a risk-benefit
21 analysis on whether to use a medical device. Do
22 you agree with me on that?

23 A Yes.

24 Q Okay. As you sit here today, you don't
25 know the context of any of these internal Bard

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1 Q Doctor, a Bard representative sat with
2 you and helped you place filters in bariatric
3 surgery patient, correct?

4 A He --

5 MS. HELM: Object to the form.

6 A He was present.

7 Q He was present while you were doing it?

8 A Yes.

9 Q And why did you want him there? Why
10 did you -- why was he is present? What was the
11 purpose of him being there?

12 A To provide information if I had
13 questions.

14 Q Okay. To help you if you needed it?

15 A To provide information. He wouldn't
16 physically help me.

17 Q At any point did he tell you, hey, you
18 shouldn't use that IVC filter with bariatric
19 patients?

20 A Not that I recall.

21 Q If -- if there was some concern within
22 Bard about -- about using IVC filters with -- with
23 bariatric patients, would you have expected him to
24 tell you that?

25 MS. HELM: Object to the form.

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1 filter --

2 A Yes.

3 Q -- you did not have all the -- based on
4 the documents you've seen here today, there are
5 things that Bard didn't tell you about risks and
6 problems with its filters, fair?

7 MS. HELM: Object to the form.

8 A Yes.

9 Q Now, Doctor, your care and treatment
10 with regard to the filters was to implant the
11 filters, fair?

12 A Yes.

13 Q You didn't do explants of the filters?

14 A No.

15 Q You didn't -- you didn't CT scan
16 filters and check for complications?

17 A No.

18 Q So when it comes to complications that
19 your patients may or may not have had, the
20 person -- you may not be the right person to talk
21 to; is that fair?

22 A If they return for follow-up, then I
23 would think that they would make me aware.

24 Q And we talked about the fact that --
25 that eventually as many as 85 percent stop

**REDACTED DOCUMENTS
RELATED TO DOCKET 7946**

**EXHIBIT D
FILED REDACTED**



Deposition of:

February 8, 2017

In the Matter of:

**In Re: Bard IVC Filters Products
Liability**

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
800.808.4958 | calendar-atl@veritext.com | 770.343.9696

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1 toll-free number is attorney-client privilege?

2 MR. DEGREEFF: To an attorney law firm, yeah.

3 MS. HELM: Okay. Before you retain them, okay.

4 BY MS. HELM:

5 Q Do you know how you got to Mr. Degreeff's
6 firm?

7 A I was transferred.

8 Q Was your call physically transferred to his
9 firm, or did you have to hang up and call back?

10 A No. Neither.

11 Q Okay. Did someone from Mr. Degreeff's firm
12 call you?

13 A I received a letter.

14 Q And without the -- I don't want to know the
15 contents of the letter.

16 A I couldn't tell you anyway.

17 Q Okay. From whom did you receive a letter,
18 someone in Mr. Degreeff's firm?

19 A The firm, yes.

20 Q Mr. Degreeff's law firm?

21 A Yes.

22 Q Okay. You -- I'm not going to go into the
23 substance, but I'm entitled to know the event. You saw
24 an ad in the fall of 2015; is that right?

25 A Yes.

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1 Q And it was an ad about IVC filters; is that
2 right?

3 A Yes.

4 Q And the ad said if you have an IVC filter, you
5 may be entitled to compensation, call this number; is
6 that right?

7 MR. DEGREEFF: Object to form.

8 Q Generally?

9 A Generally.

10 Q Okay. You called the toll-free number, you
11 spoke to someone, and then without going into the
12 substance of the conversation, the next event was you
13 received a letter from Mr. Degreeff's firm; is that
14 right?

15 A Correct.

16 Q Okay. Have you signed an agreement or a
17 contract of some kind with Mr. Degreeff's law firm?

18 MR. DEGREEFF: If you know.

19 A I'm not -- I'm not sure.

20 Q Okay. When did Mr. Degreeff or his law firm
21 become your lawyers?

22 MR. DEGREEFF: Object to the form.

23 A Shortly after -- after calling the number. I'm
24 not certain of the date.

25 Q I think in your information you provided to us

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1 you -- you're welcome to look and correct me. It's on
2 page 2 of Exhibit 2, the big one. And on page 2 under
3 paragraph 1E, it says you first retained a lawyer on
4 October 14, 2015. Does that sound right?

5 A That does.

6 Q Okay. So you saw the ad sometime before
7 October 14, 2015; is that right?

8 A Just a matter of a week or so, yes.

9 Q Okay. Saw the ad, you made the phone call,
10 and subsequently got a -- at least got a letter from Mr.
11 Degreeff's firm; is that right?

12 A Correct.

13 Q Okay. Okay. Other than that one phone call,
14 the one toll-free number from the ad you saw, did you
15 reach out to any other lawyers or law firms?

16 A No.

17 Q Okay. And did you make the call after --
18 after you saw the ad for the very first time?

19 A No.

20 Q Okay. You had seen the ad more than once?

21 A Yes.

22 Q Or had you seen more than one ad?

23 A I don't believe I saw more than one ad.

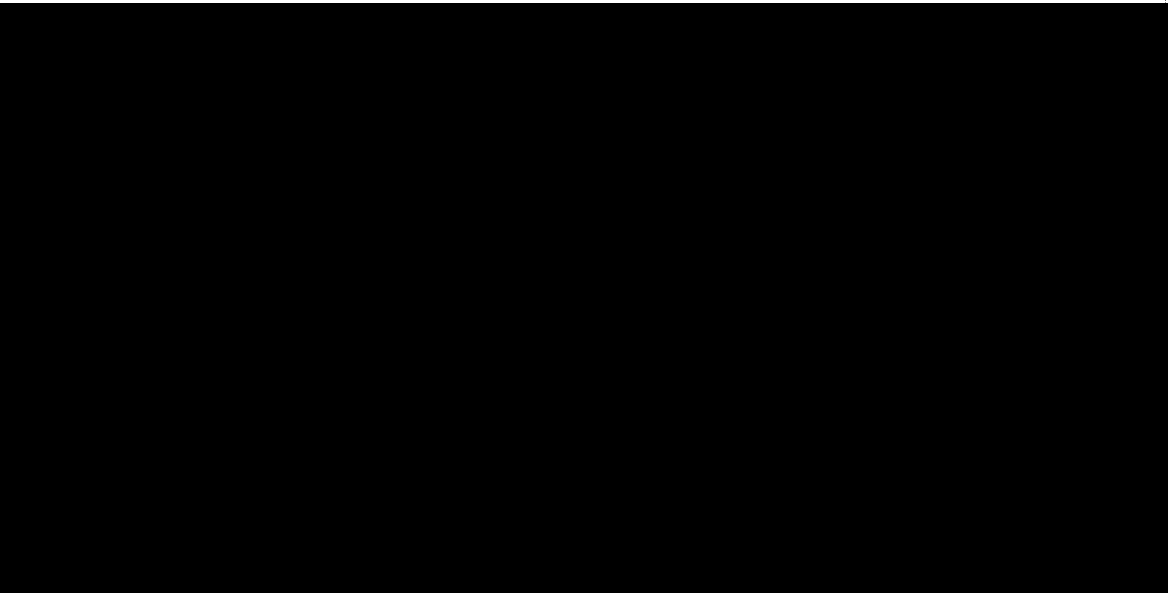
24 Q Okay. And when did you first start seeing the
25 ads?

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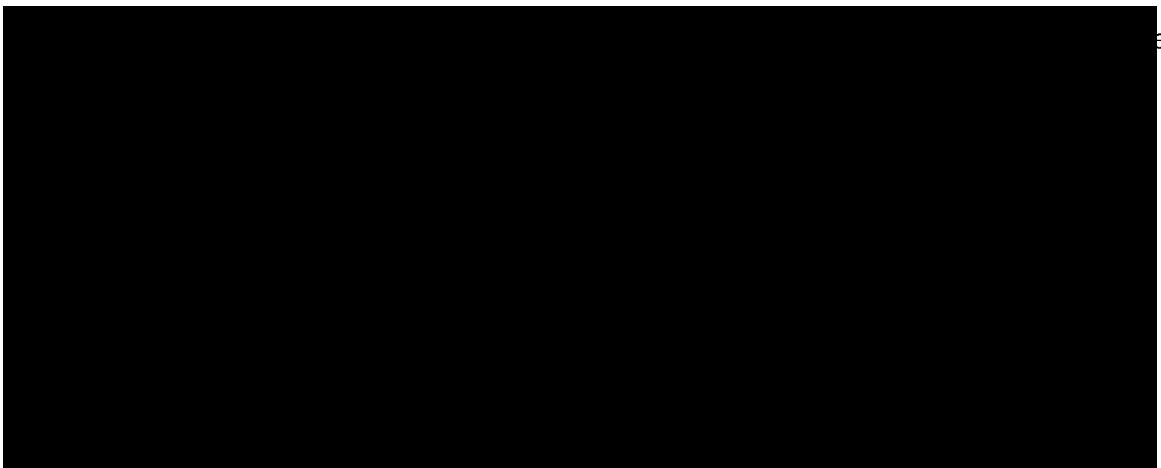
1 BY MS. HELM:



11 A No.



15 A Correct.



23 A Correct.

24 Q Okay. And in that discussion, what do you
25 recall him telling you?

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Q Right.

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A Correct.

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Q Okay.

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[REDACTED]

[REDACTED]

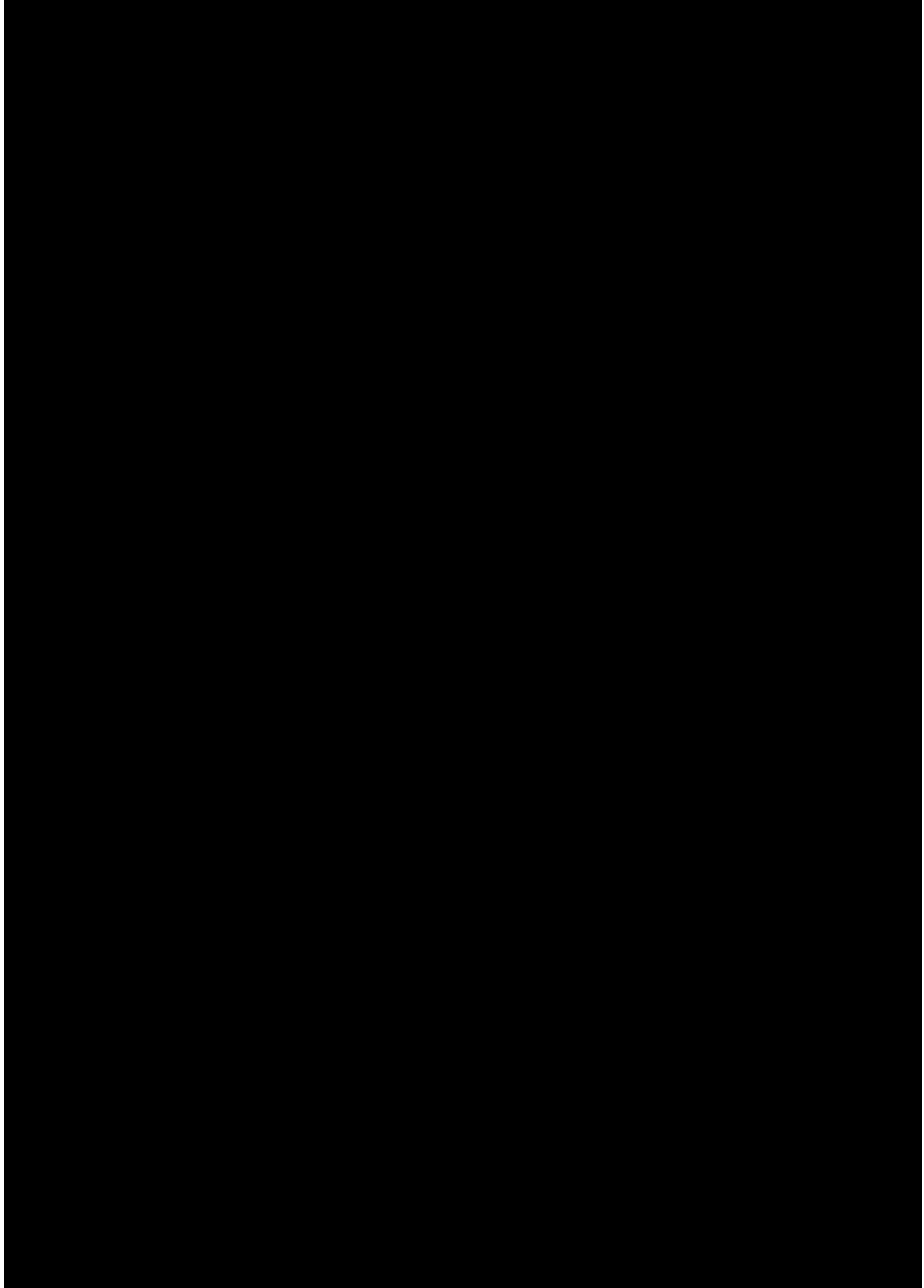
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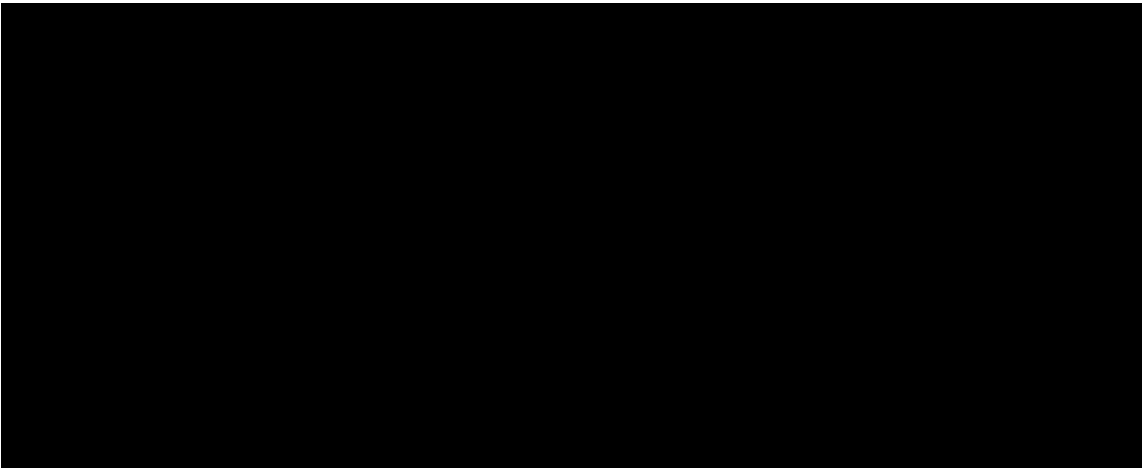


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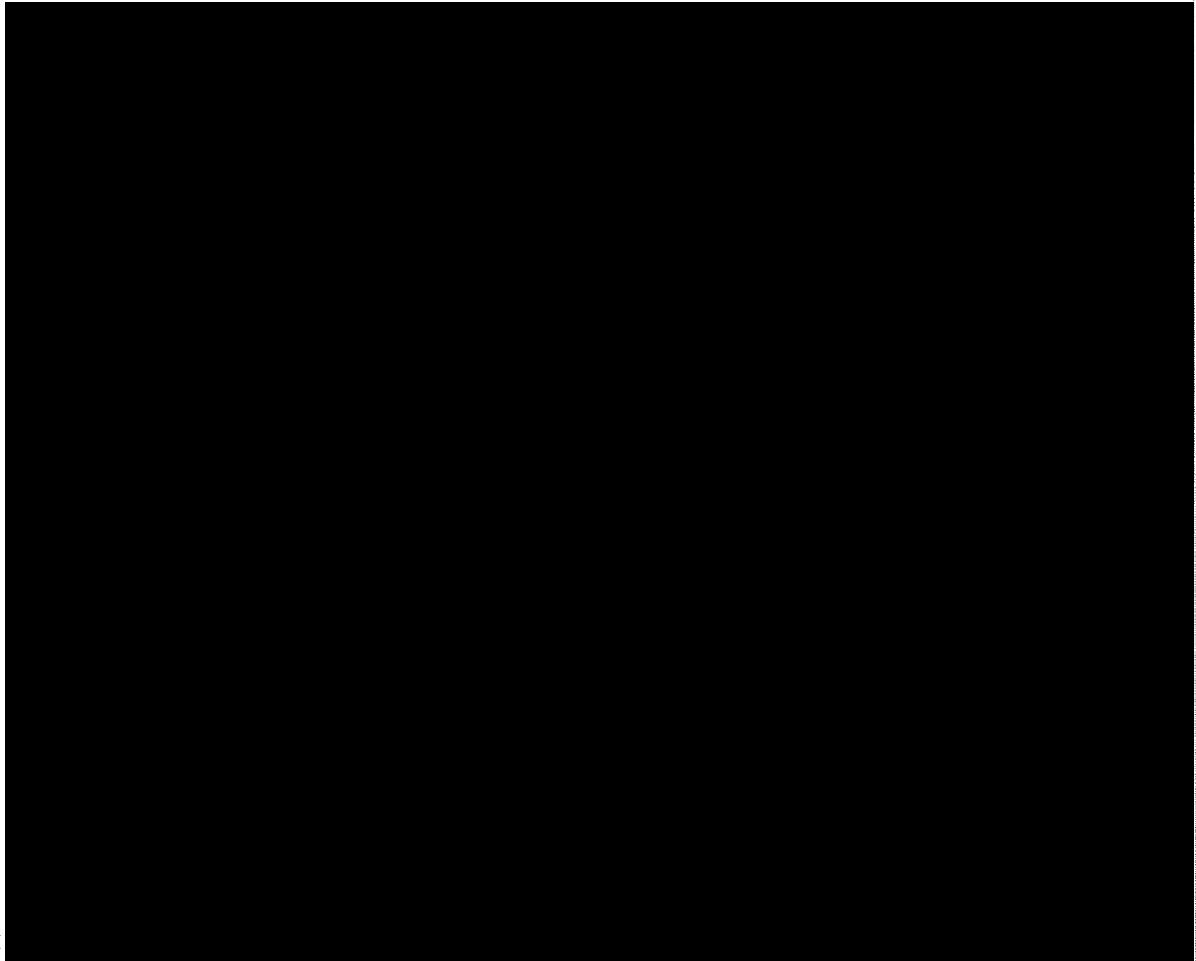
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MR. DEGREEFF: Object to form.

A I assumed there was. There are with
everything.

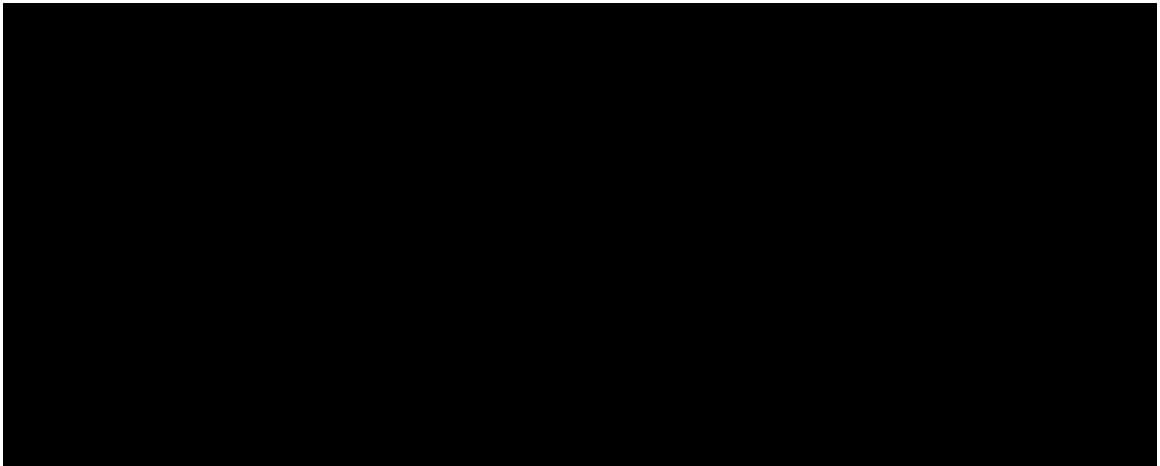


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A It sounds right.

Q Okay.

A I'm not sure on that.

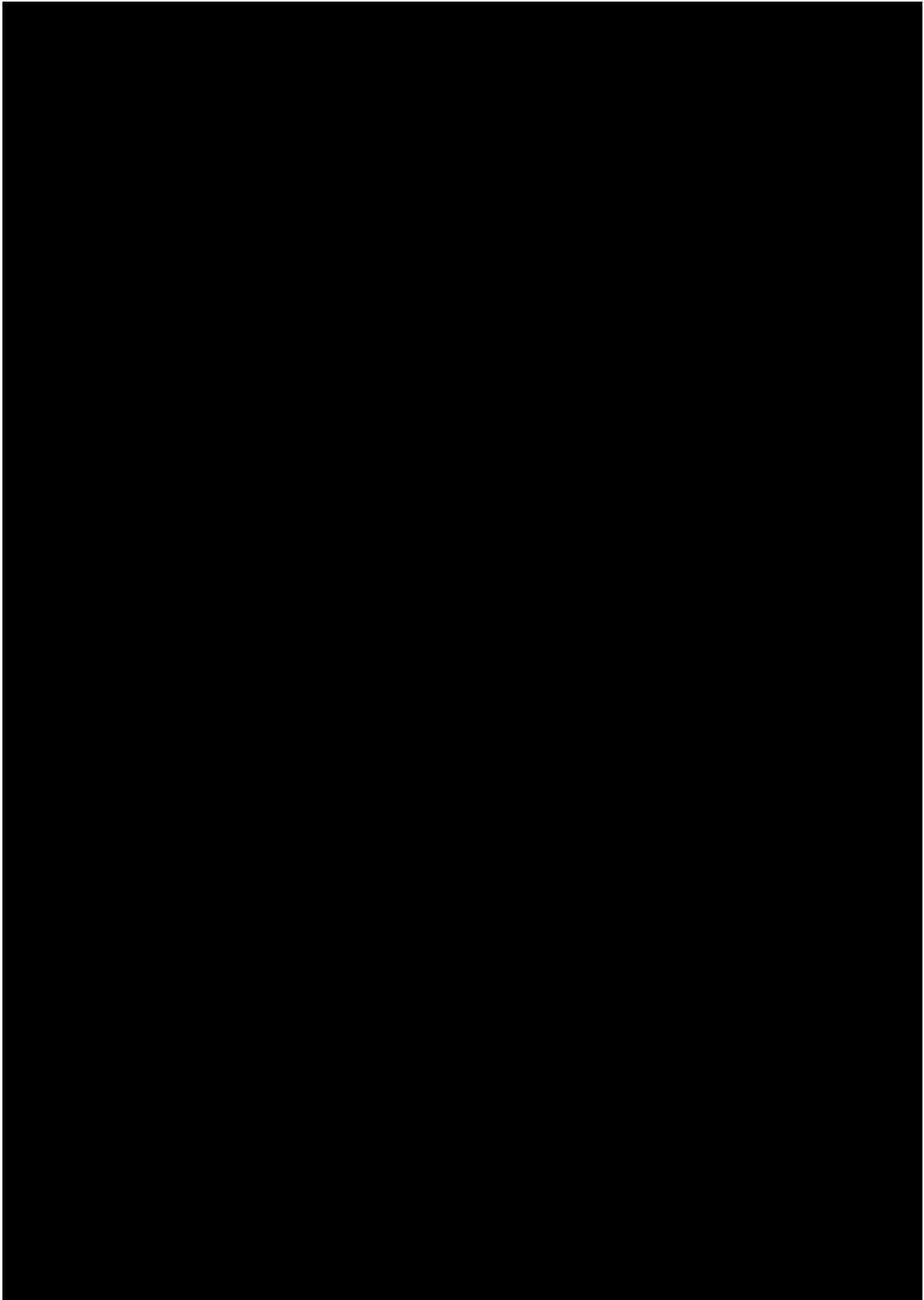


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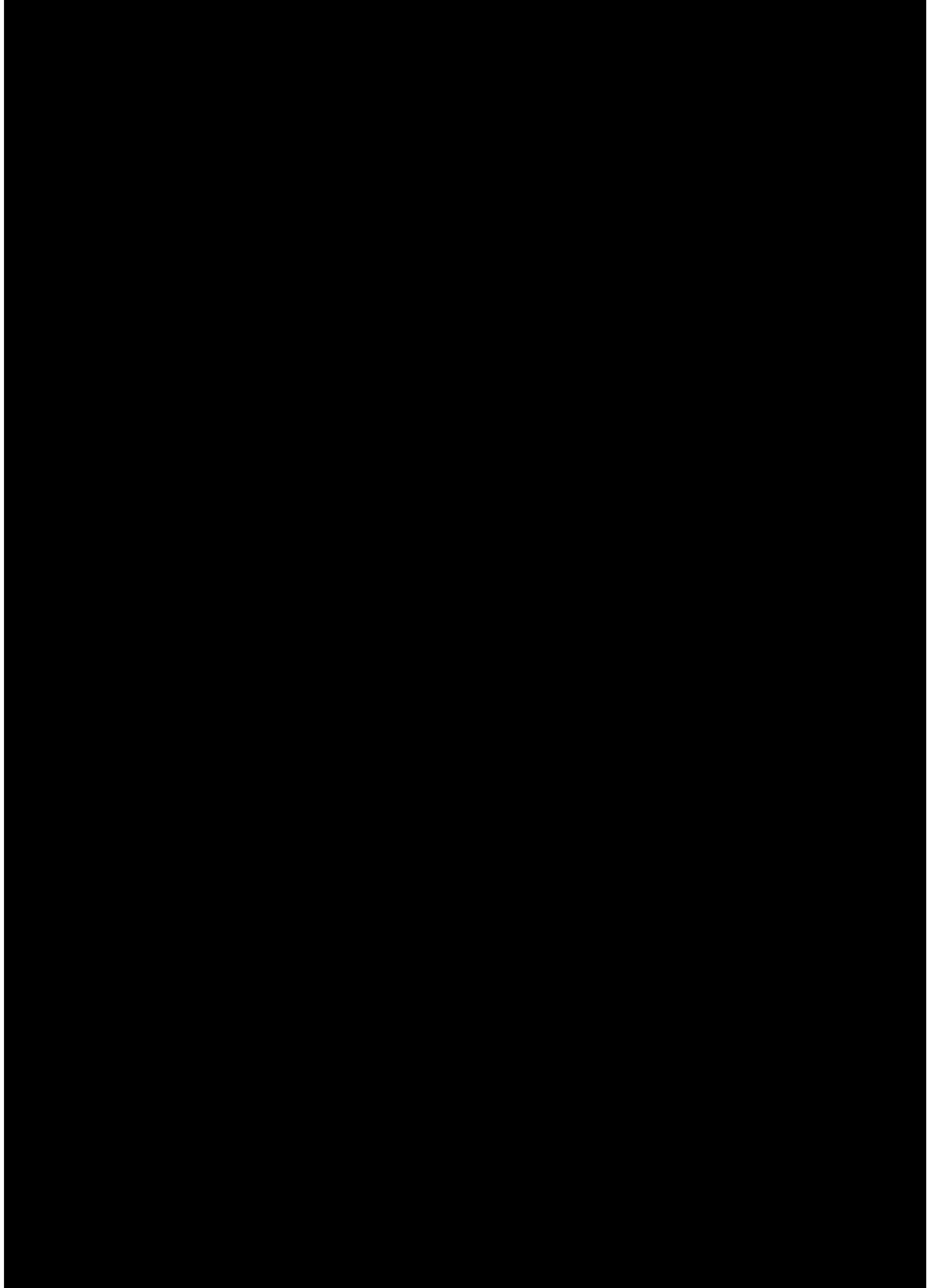


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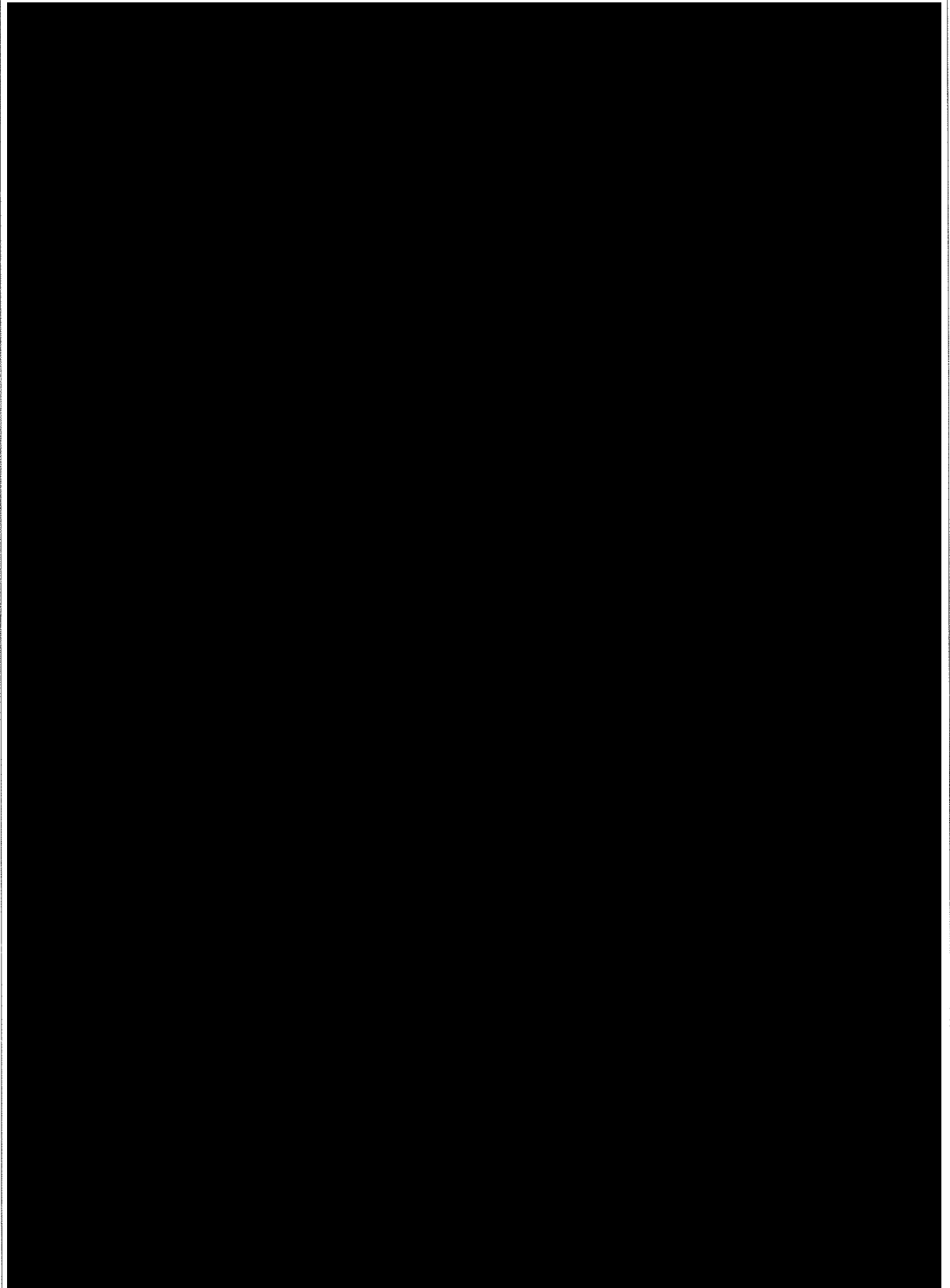


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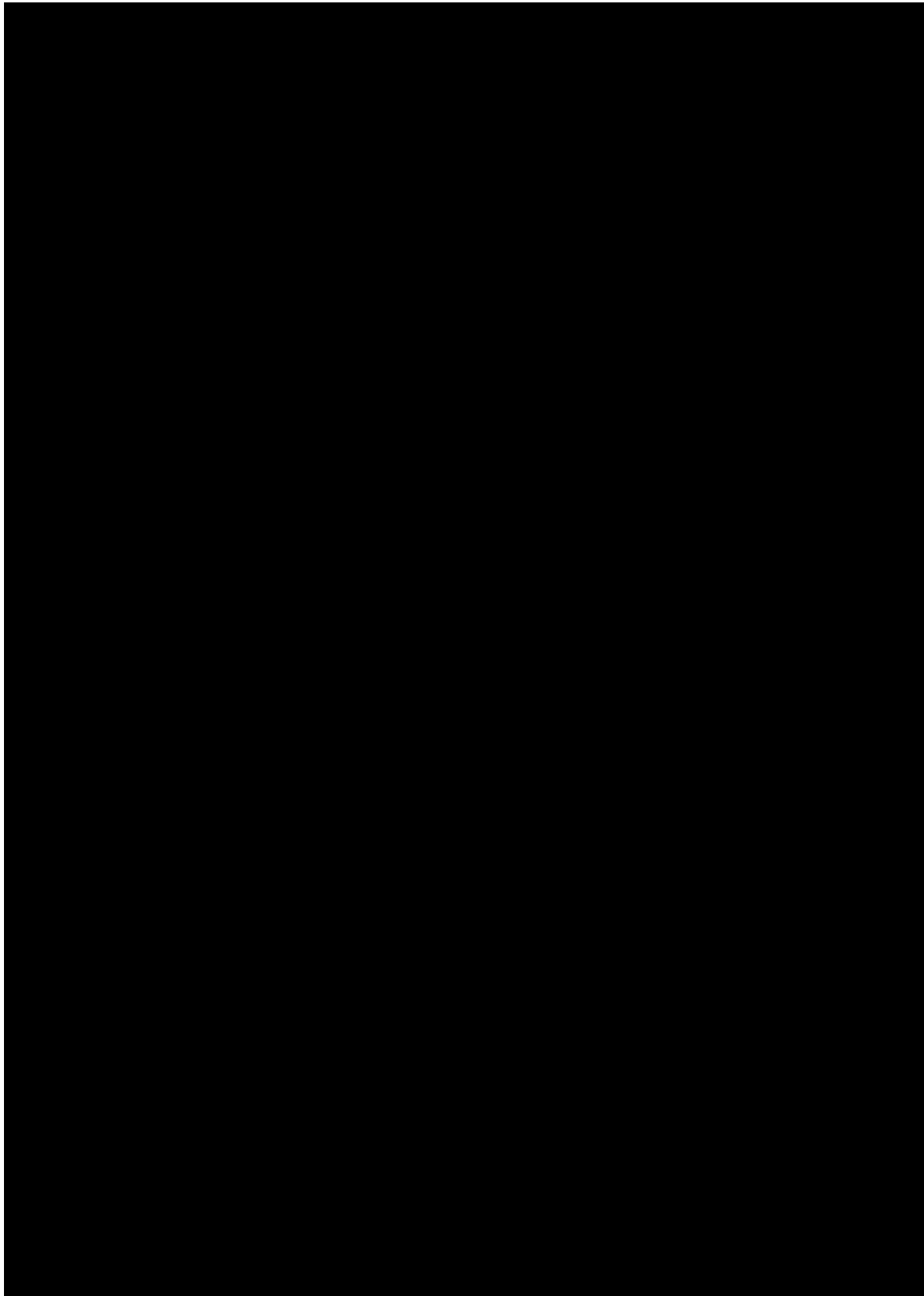


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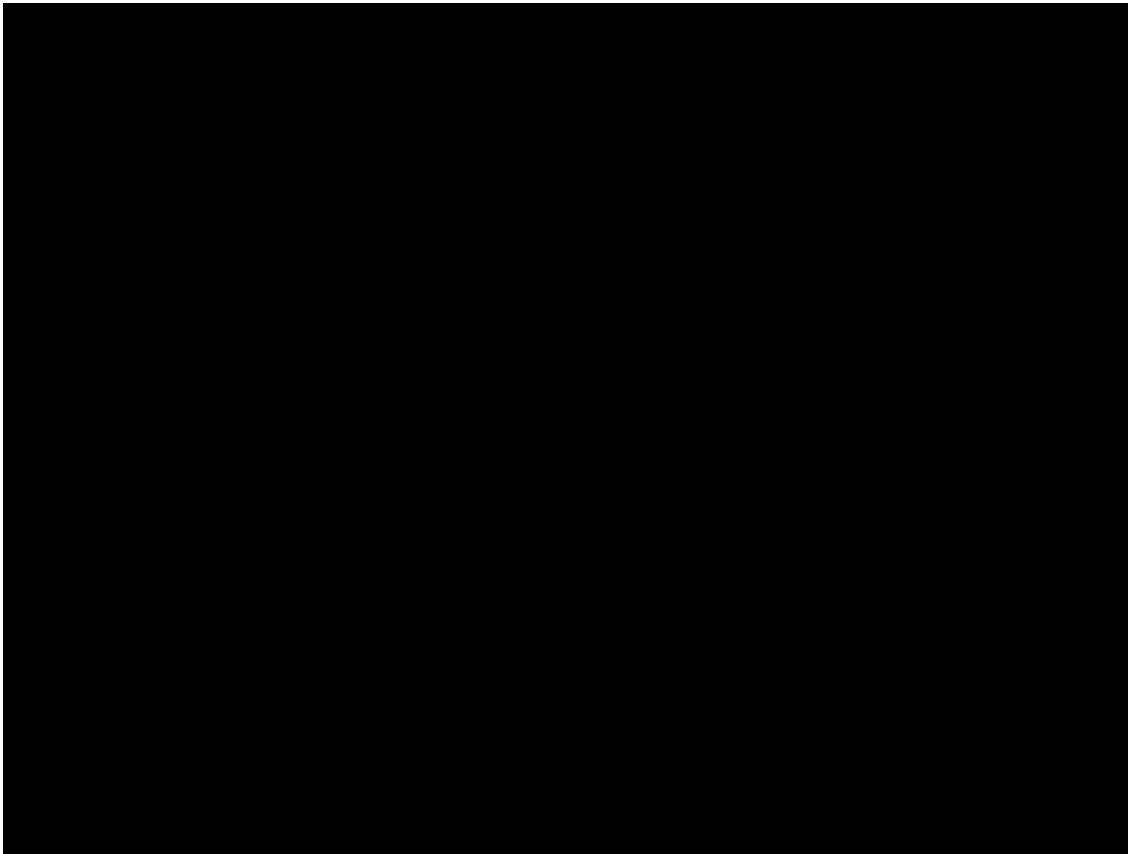


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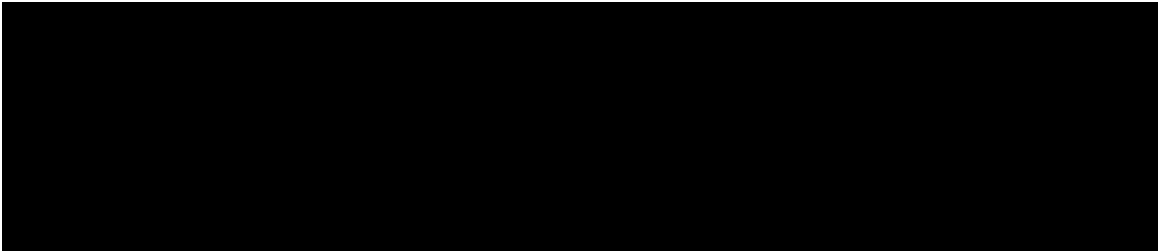


MR. DEGREEFF: Just to the extent that that
would require you to discuss conversations you had
with your attorneys, then I instruct you not to
answer.

BY MS. HELM:

Q Can you answer that question without revealing
conversations you had with your attorney?

A No.



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1 MS. HELM: Okay.

2 BY MS. HELM:

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7 MR. DEGREEFF: Object to form.

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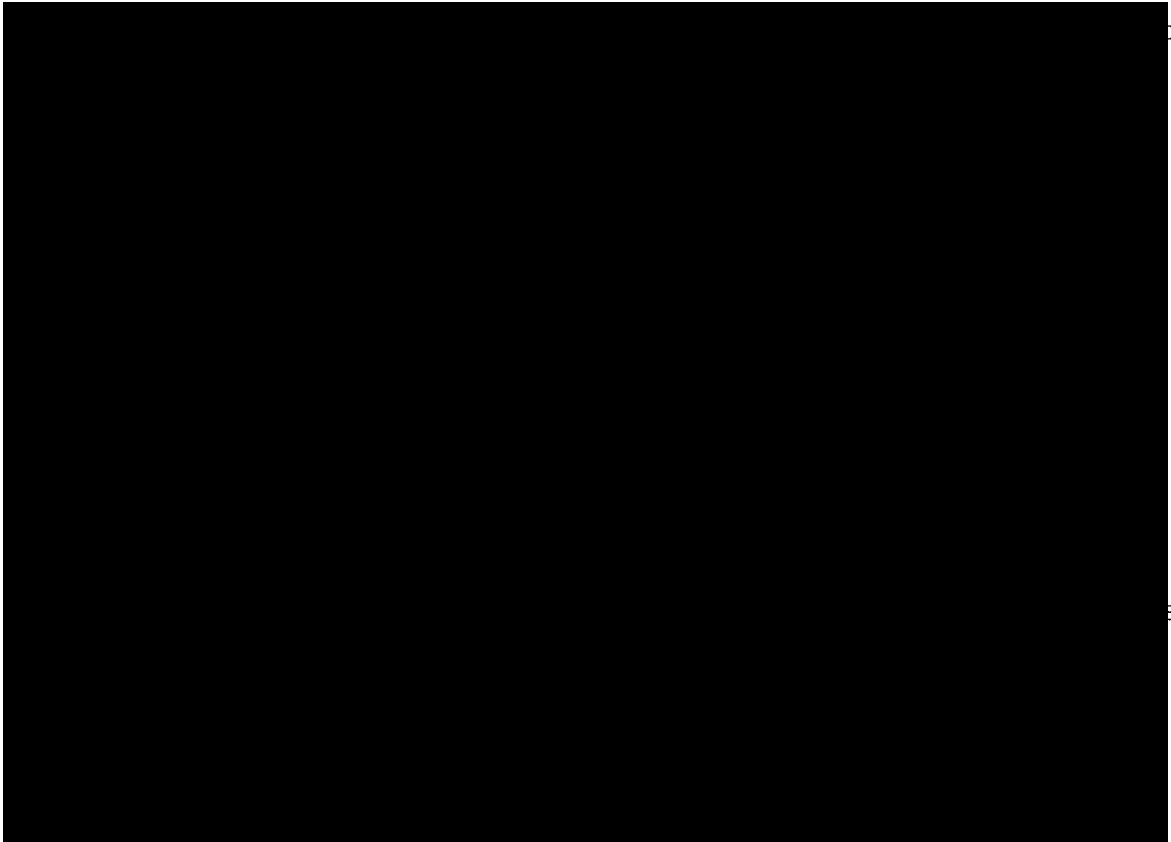
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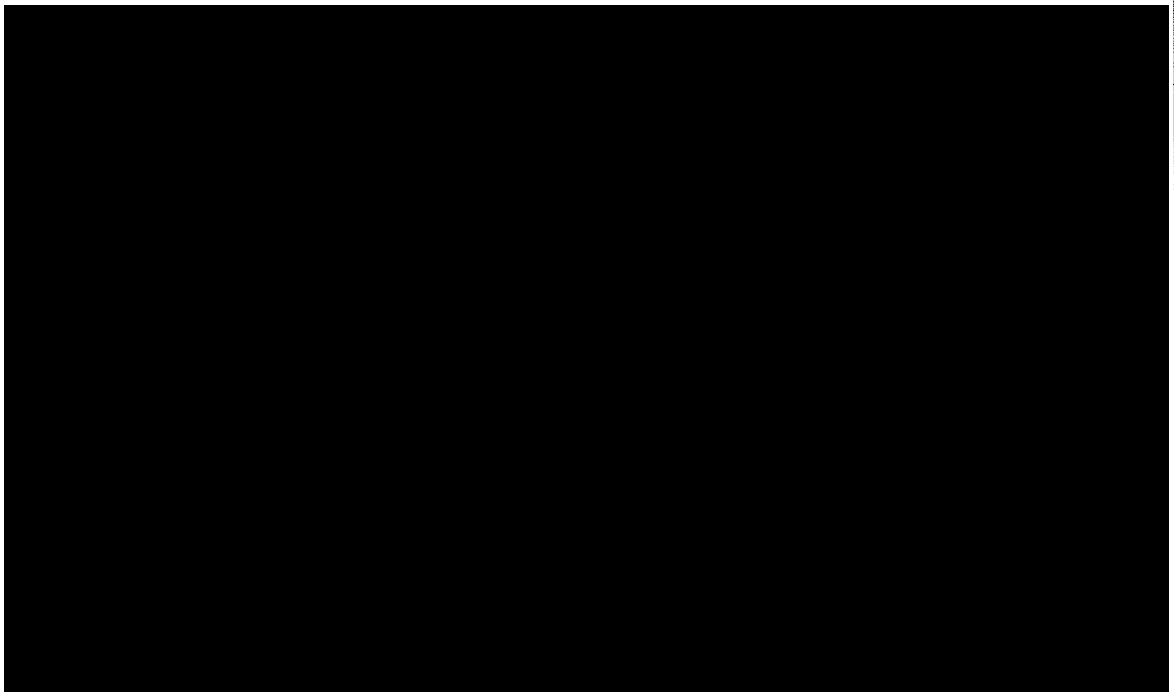
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MR. DEGREEFF: Object to form.

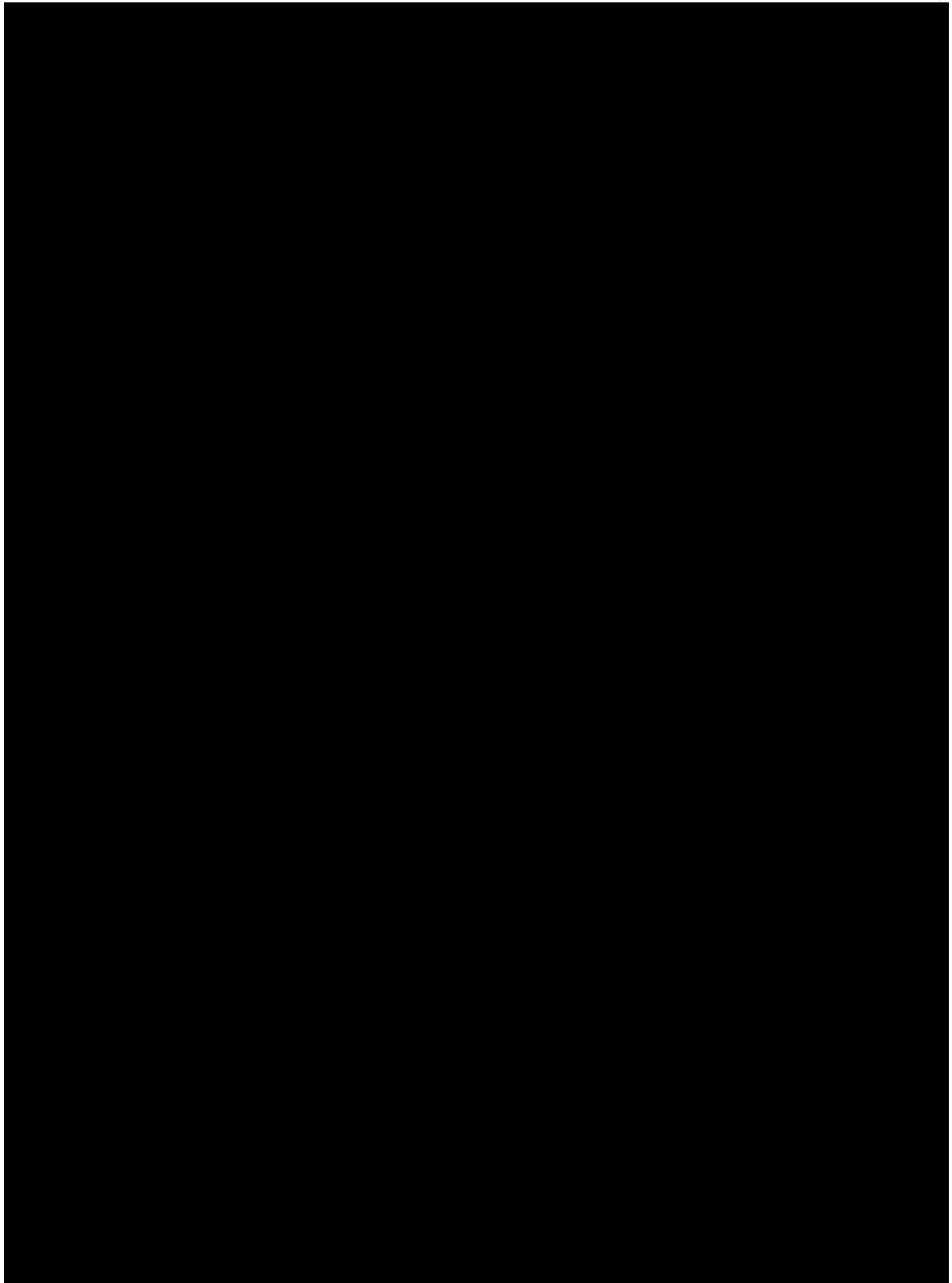


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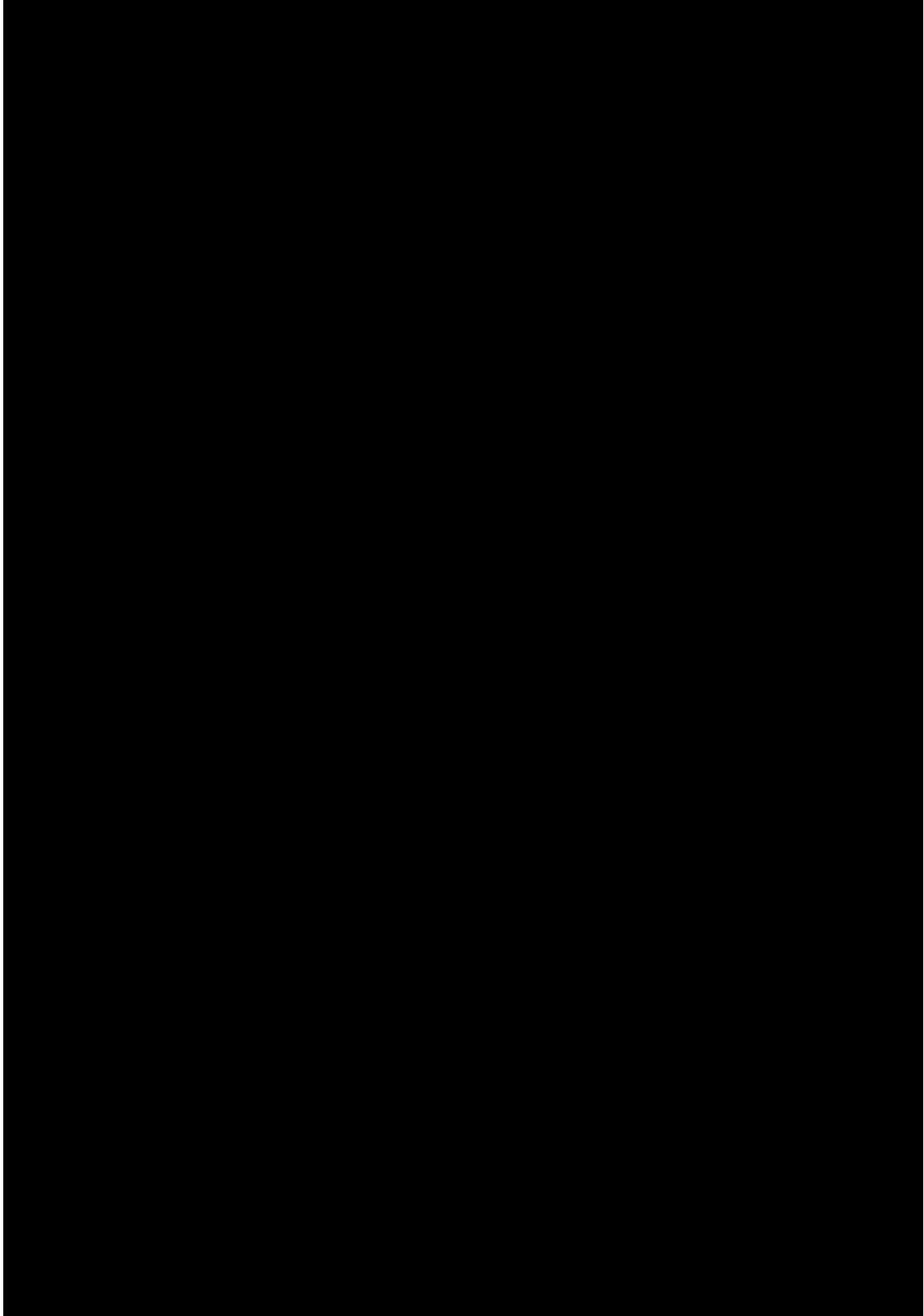


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1 Q Okay.

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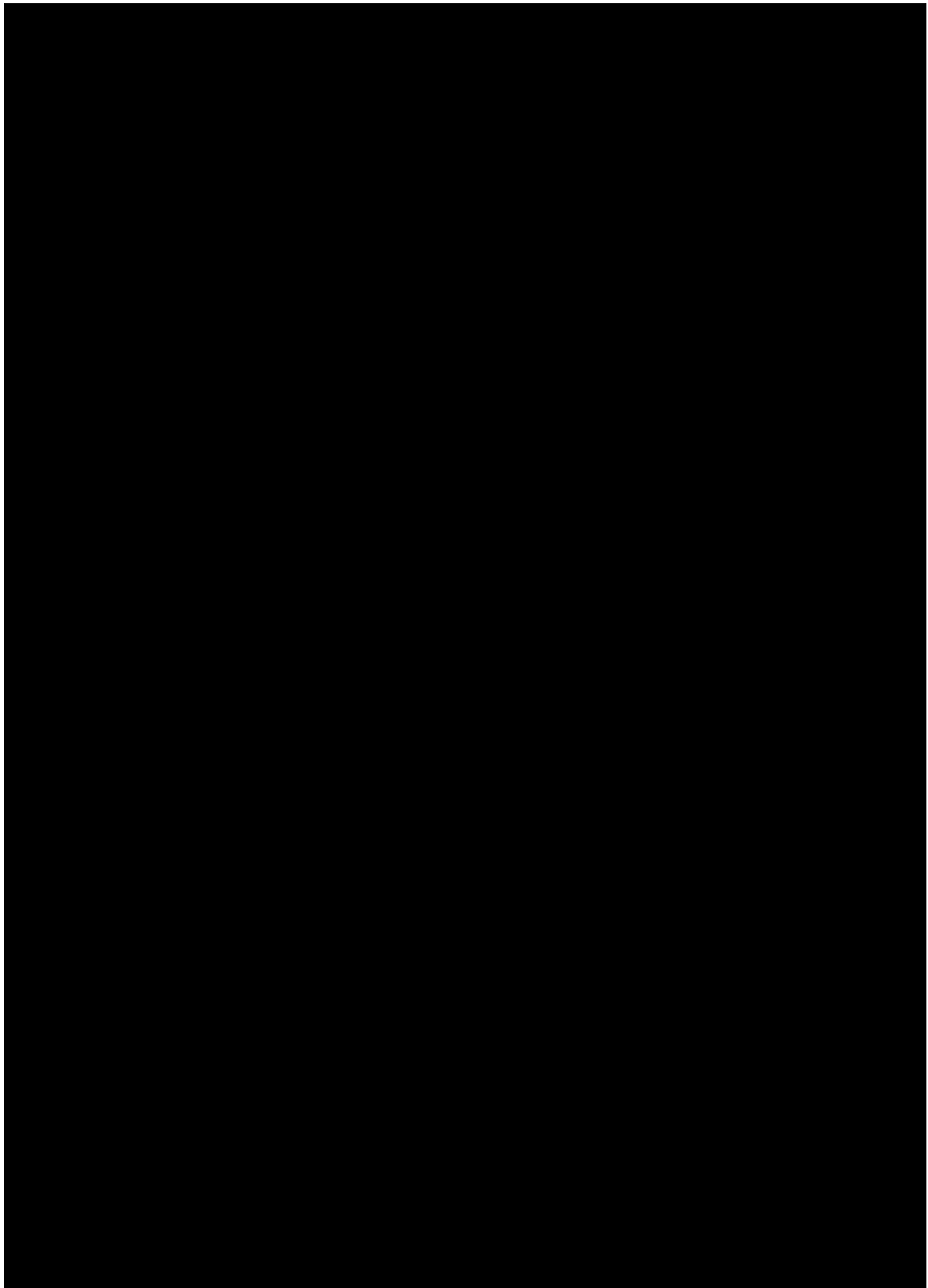
25 Q Okay. So you just spent that -- you just

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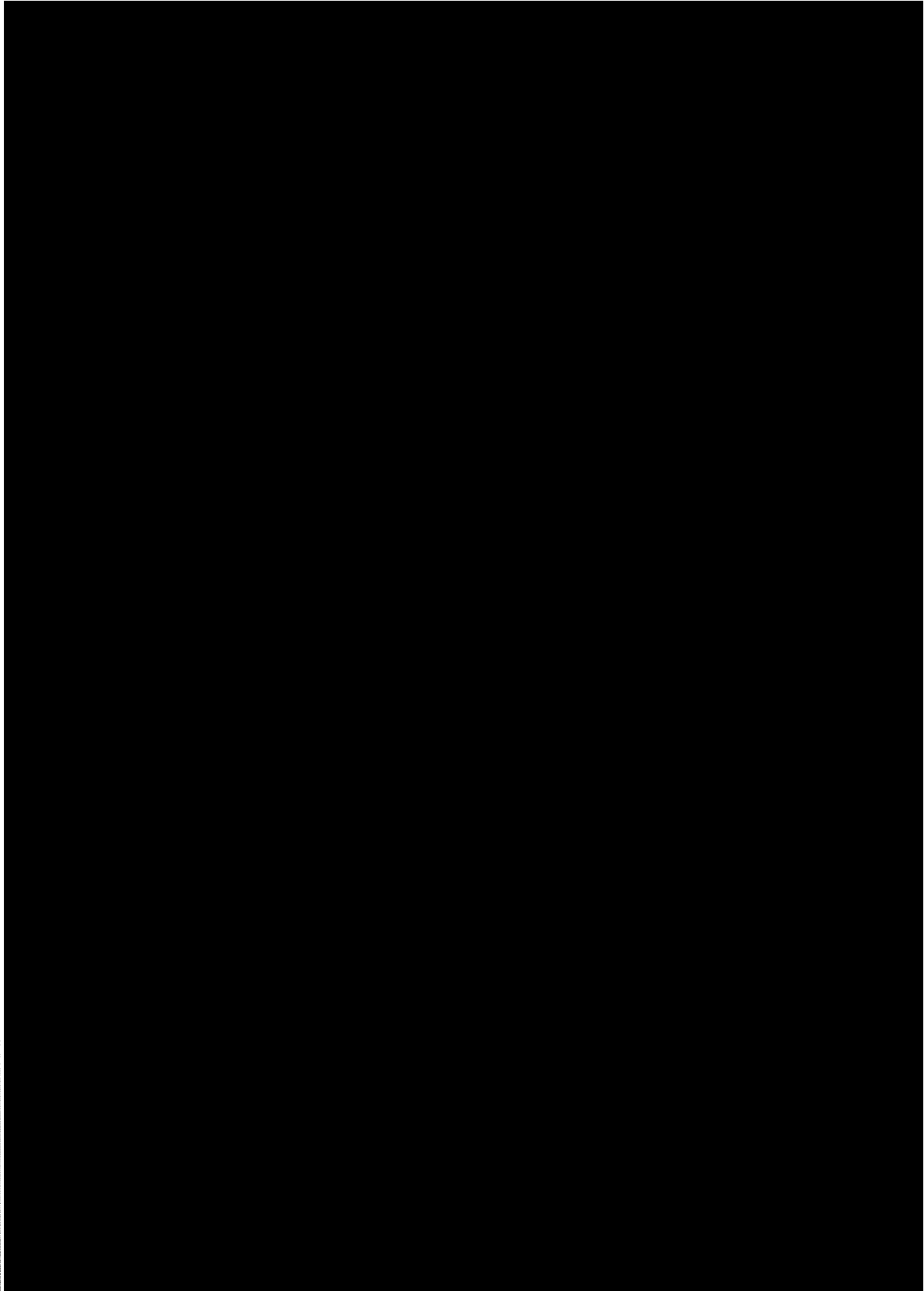
770.343.9696

Debra Mulkey
In Re: Bard IVC Filters Products Liability

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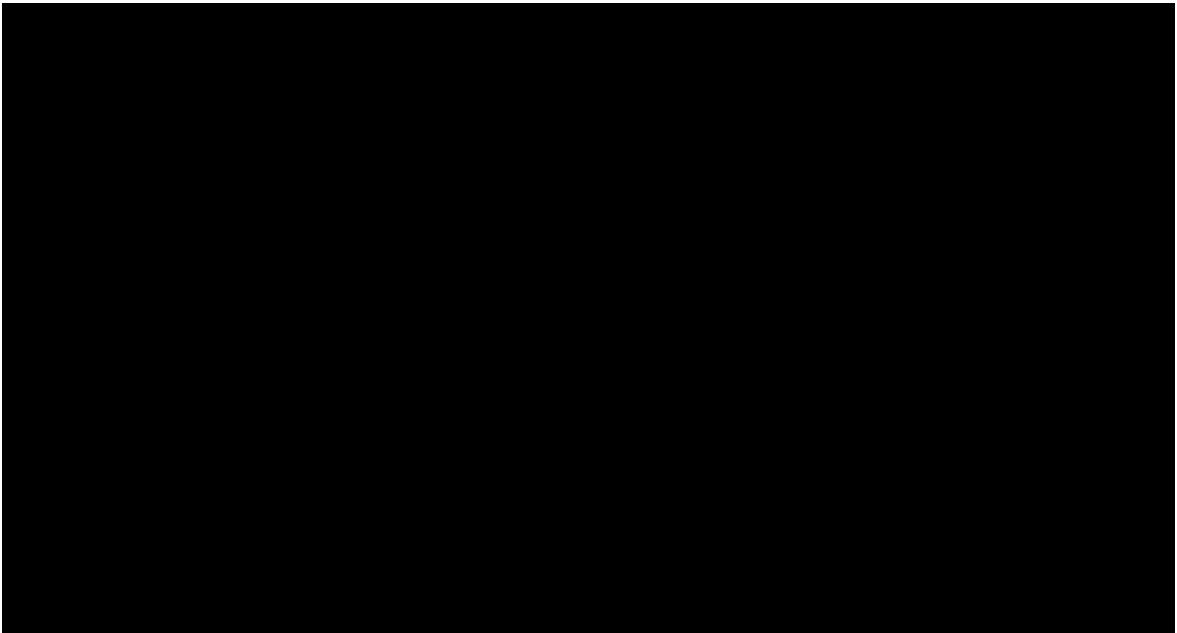


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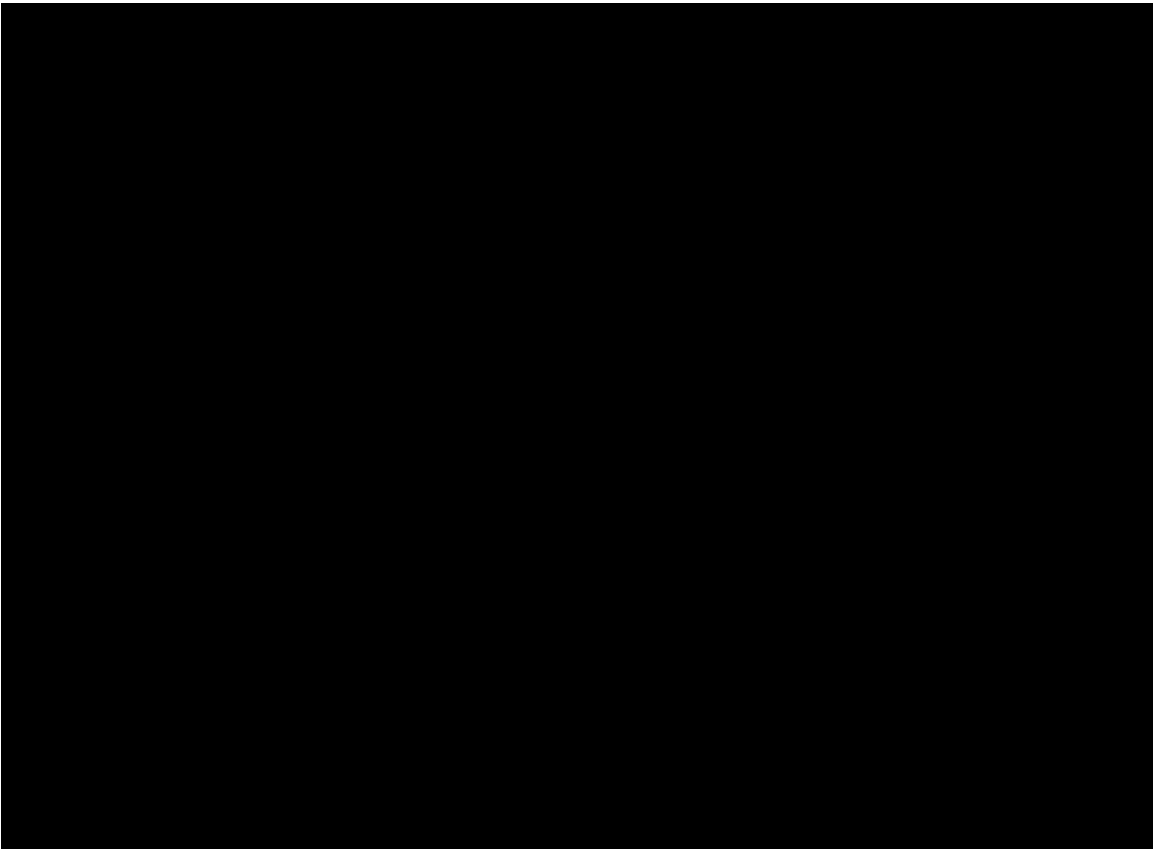
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Q So you -- this is your answer under oath --

A That is my answer.



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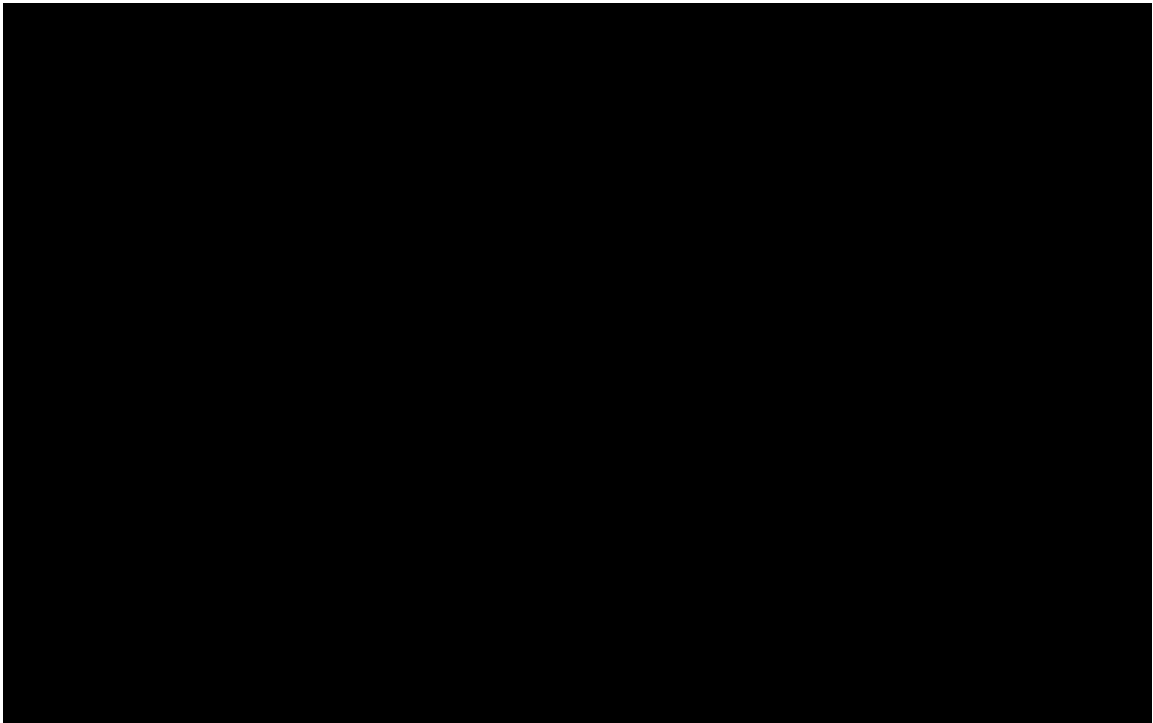
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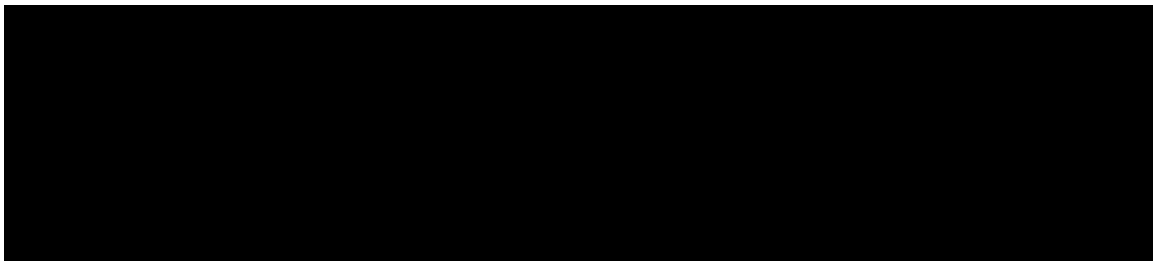
A No.

Q Correct?



Q Okay. But that's not the question. You agree with me, right? That's not the question?

A Yeah, that's kind of right up there with the symptom one, yeah.

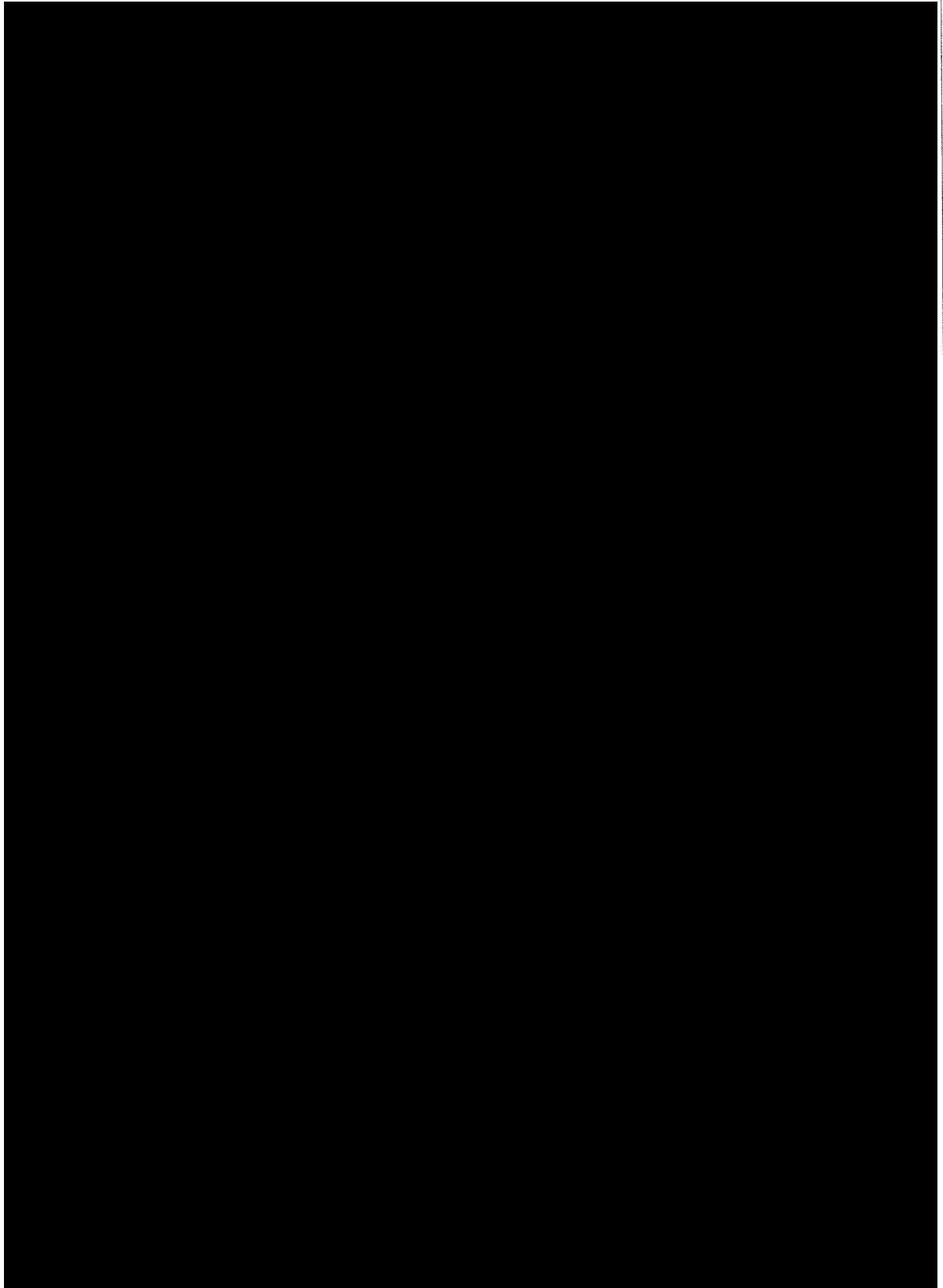


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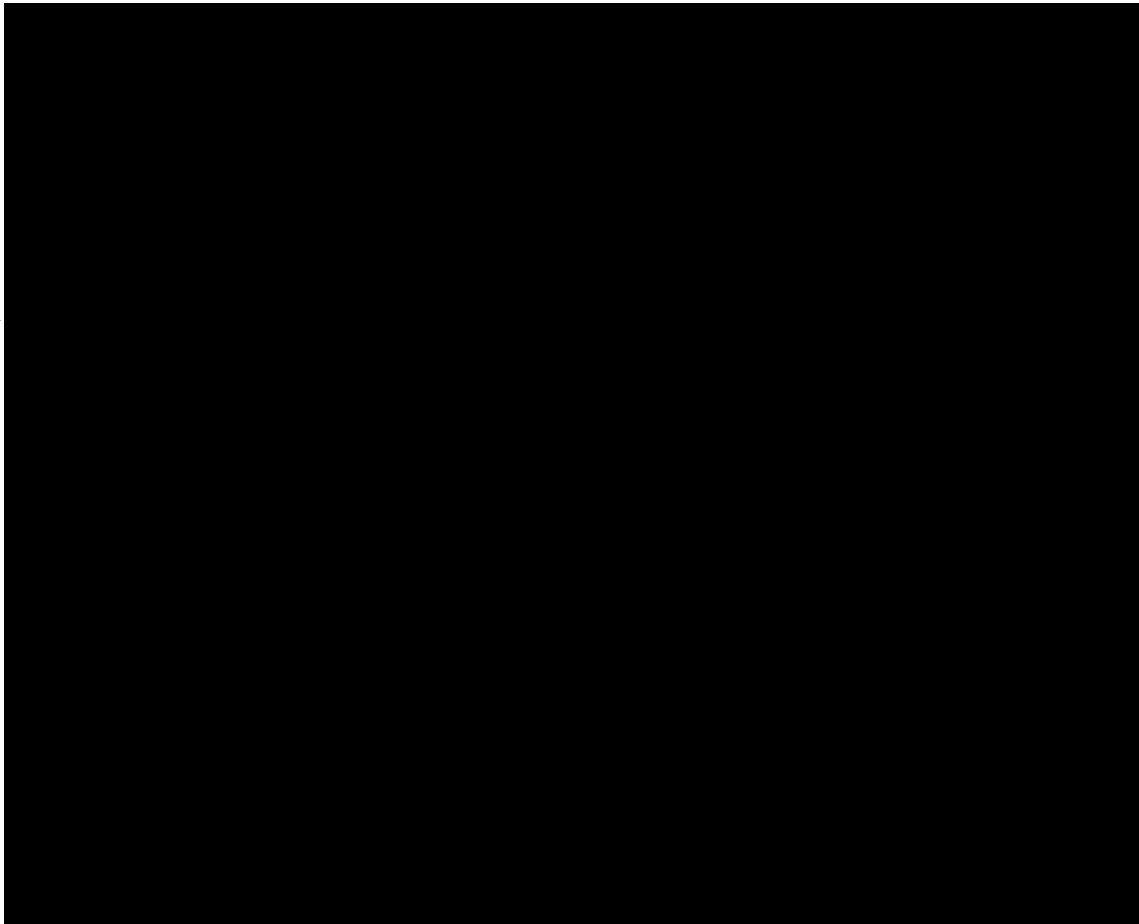


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MR. DEGREEFF: Object to form.

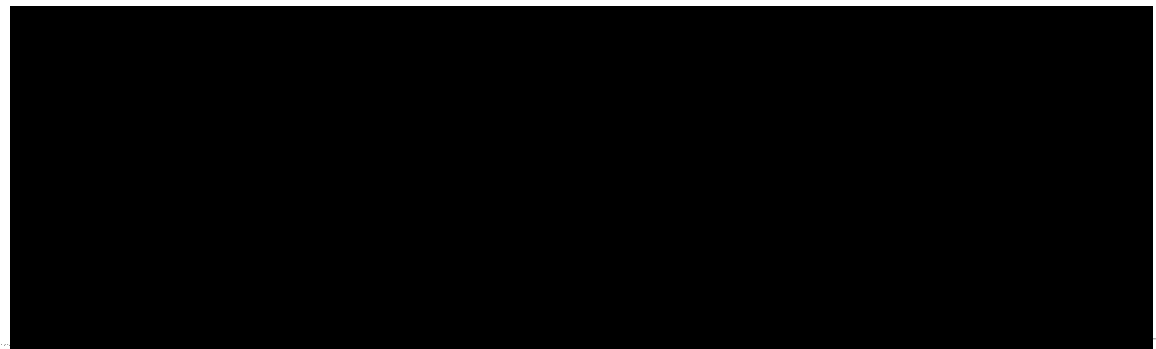
A Yes.

MS. HELM: I think that's all I have.

MR. DEGREEFF: I've got a few questions.

CROSS EXAMINATION

BY MR. DEGREEFF:

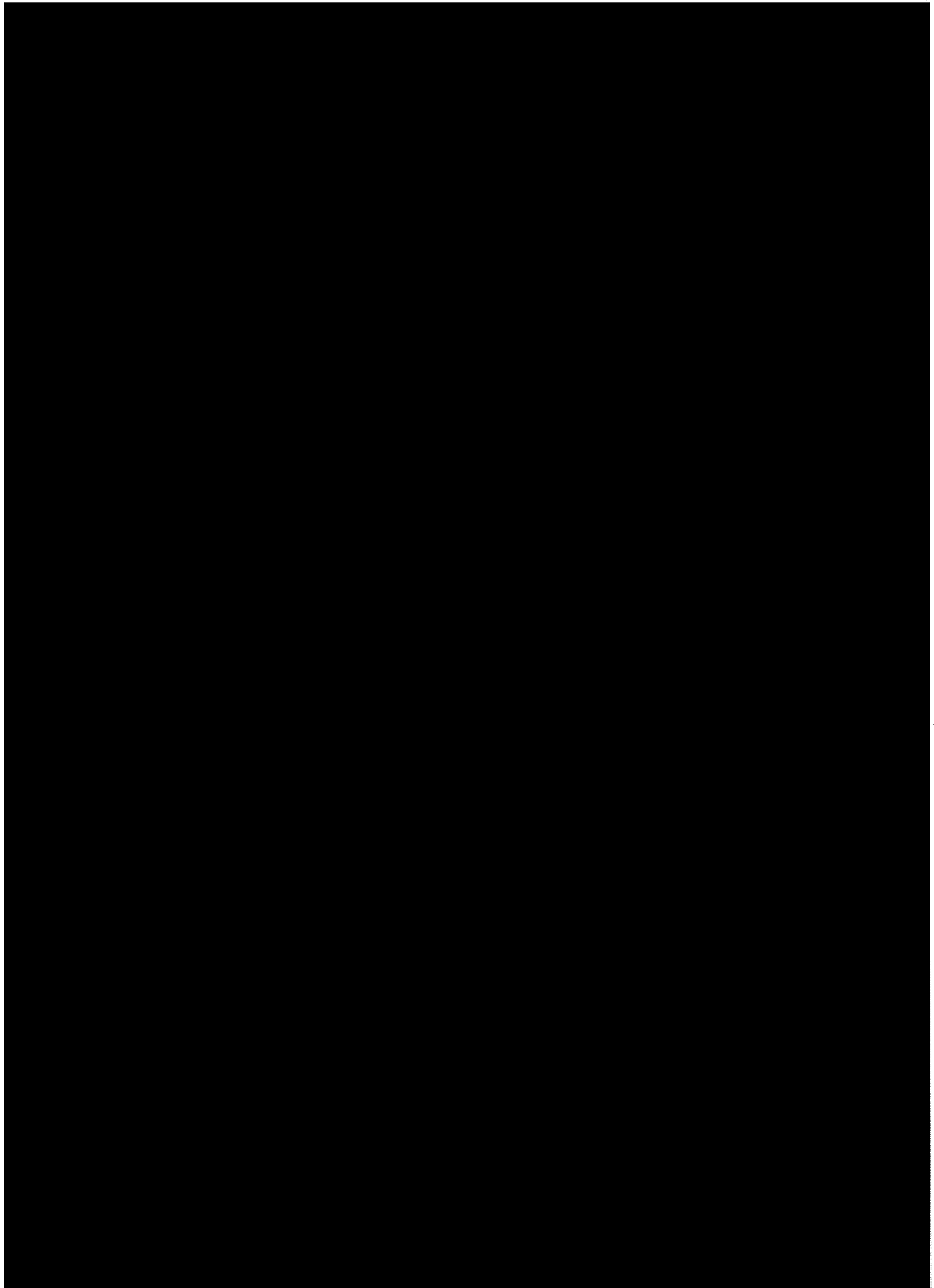


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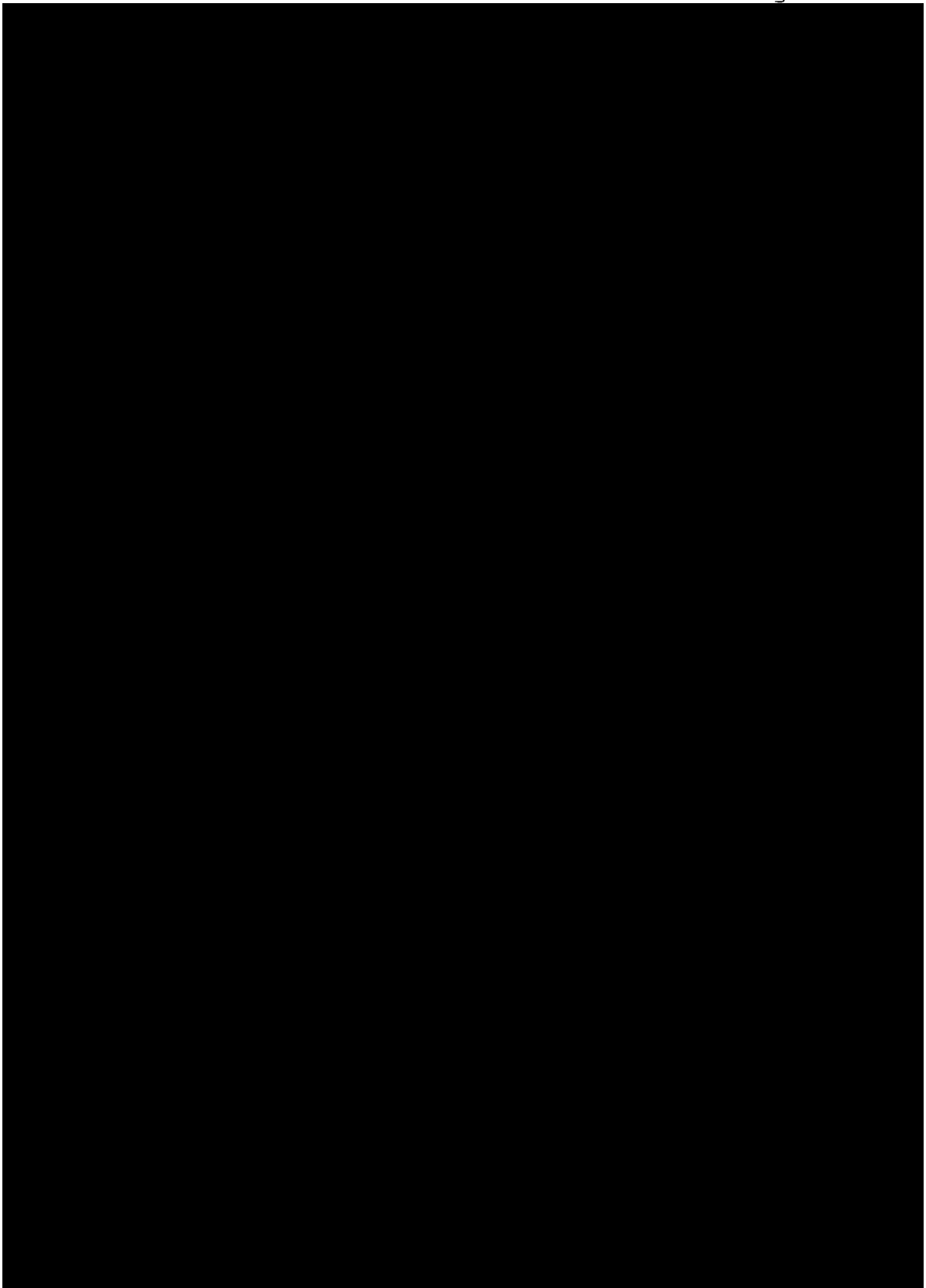


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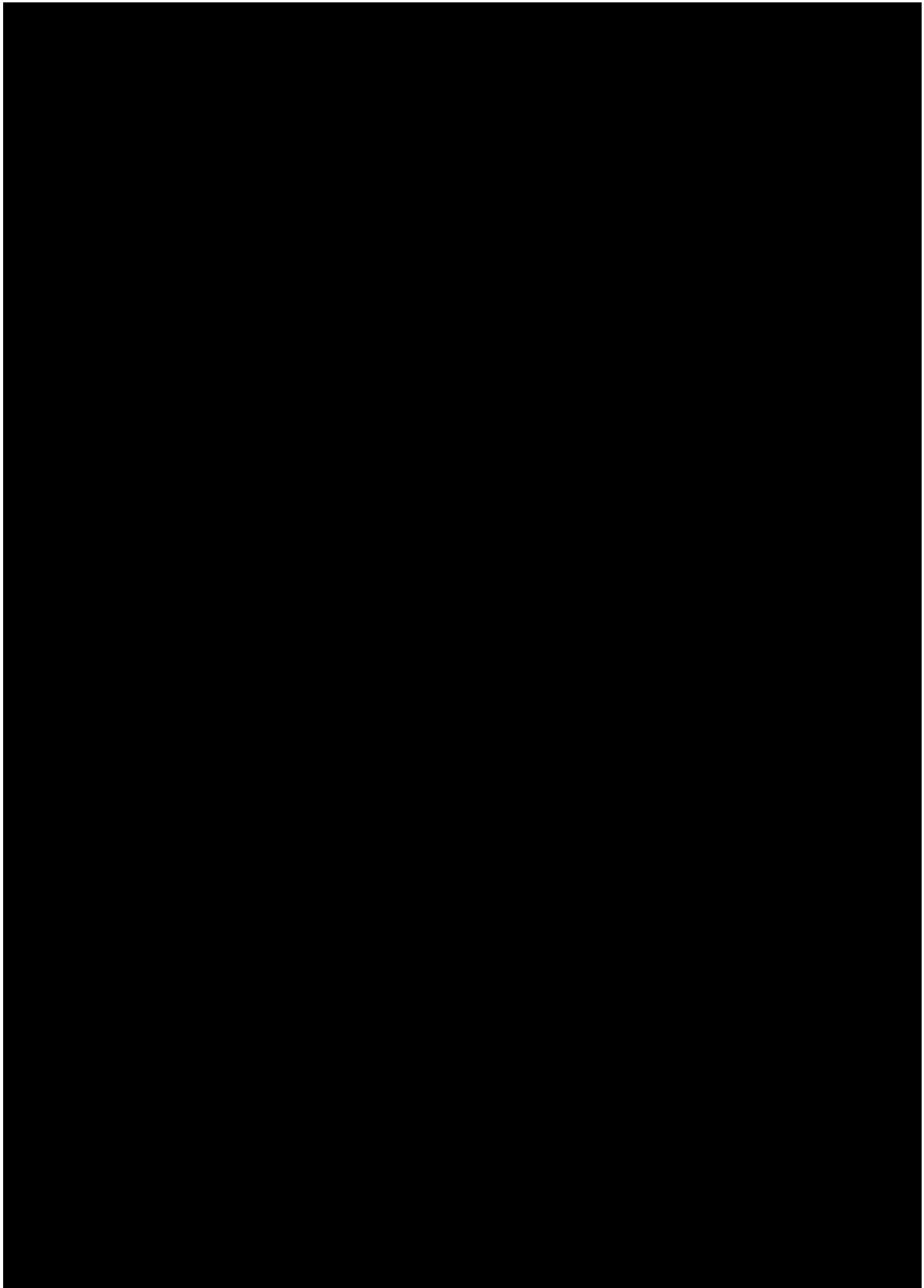


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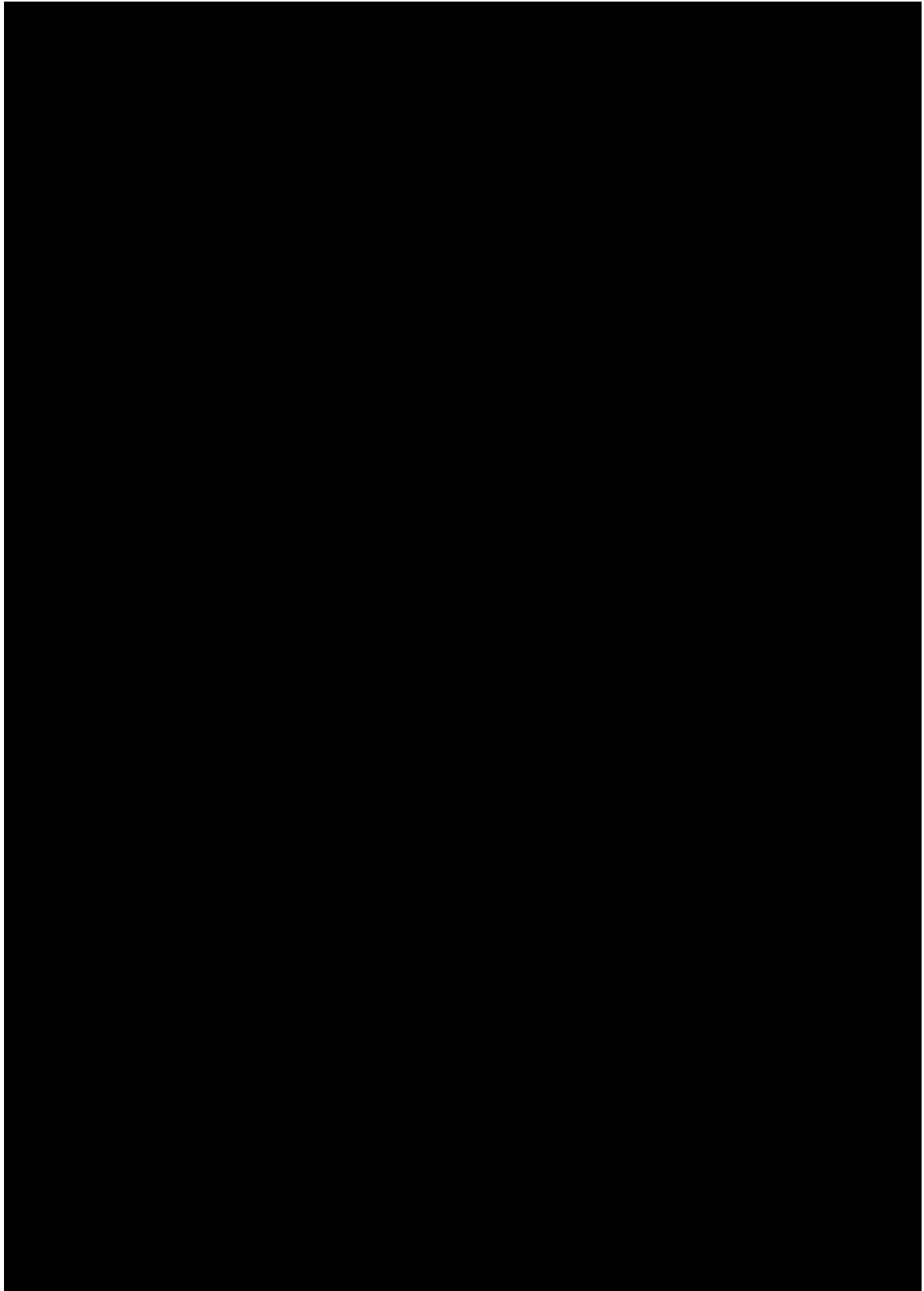


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**REDACTED DOCUMENTS
RELATED TO DOCKET 7946**

**EXHIBIT D
FILED REDACTED**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

MDL No. 2641

In Re Bard IVC Filter Products Liability Litigation

PLAINTIFF FACT SHEET

Each plaintiff who allegedly suffered injury as a result of a Bard Inferior Vena Cava Filter must complete the following Plaintiff Fact Sheet ("Plaintiff Fact Sheet"). In completing this Fact Sheet, you are **under oath and must answer every question.** You must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details as requested, please provide as much information as you can and then state that your answer is incomplete and explain why, as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet for himself/herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Bard Defendants from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, "healthcare provider" shall mean any medical provider, doctor, physician, surgeon, pharmacist, hospital, clinic, medical center, physician's office, infirmary, medical/diagnostic laboratory, or any other facility that provides medical care or advice, along with any pharmacy, x-ray department, radiology department, laboratory, physical therapist/physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in your diagnosis, care and/or treatment.

In filling out this form, the terms "You" or "Your" refer to the person who received a Bard Inferior Vena Cava Filter manufactured and/or distributed by C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. ("Bard Defendants") and who is identified in Question 1(a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary. Please identify any documents that you are

producing responsive to a question with Bates Stamp identifiers. Information provided by Plaintiff will only be used for the purposes related to this litigation and may be disclosed only as permitted under the protective order in this litigation.

I. BACKGROUND INFORMATION

1. Please state:

- (a) Full name of the person who received the Bard inferior vena cava filter, including maiden name: [REDACTED] - Maiden Name: [REDACTED]
- (b) List all names by which you have ever been known, if different from that listed in 1(a): [REDACTED]
- (c) Full name of the person completing this form, if different from the person listed in 1(a) above, and the relationship of the person completing this form to the person listed in 1(a) above: _____
- (d) The name and address of your primary attorney:
David C. DeGreeff
Wagstaff & Cartmell LLP
4740 Grand Ave., Ste. 300
Kansas City, MO 64112
- (e) When did you first retain an attorney to represent you in your lawsuit against Bard?
10/14/2015

2. Your Social Security Number: [REDACTED]

3. Your Date of Birth: [REDACTED]

4. Your current residential address:

[REDACTED]

5. If you have lived at this address for less than 10 years, provide each of your prior residential addresses from 2000 to the present:

Prior Residential Address	Dates You Lived At This Address
---------------------------	---------------------------------

[REDACTED]	

6. Have you ever been married? Yes [REDACTED] No [REDACTED]
 If yes, provide the names and addresses of each spouse and the inclusive dates of your marriage to each person:

[REDACTED]

7. Do you have children? Yes [REDACTED] No [REDACTED]
 If Yes, please provide the following information with respect to each child:

Full Name of Child	Date of Birth	Home Address	Whether Biological/Adopted
[REDACTED]			

8. Identify the name and age of any person who currently resides with you and their relationship to you:

[REDACTED]

9. Identify the name and age of any person who has resided with you at any point over the past ten (10) years:

[REDACTED]

10. Identify all secondary and post-secondary schools you attended, starting with high school, and please provide the following information with respect to each:

Name of School	Address	Dates of Attendance	Degree Awarded	Major or Primary Field of Study

11. Please provide the following information for your employment history over the past 10 years up until the present:

Employer Name	Address	Job Title/Description of Duties	Dates of Employment	Salary/Rate of Pay

12. Have you ever served in any branch of the military? Yes _____ No X

If Yes, please provide the following information:

- (a) Branch and dates of service, rank upon discharge, and type of discharge received:

- (b) Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? Yes _____ No _____

If Yes, state what that condition was: _____

13. Within the last ten years, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? Yes _____ No X _____

If Yes, please set forth where and when and identify the felony and/or crime:

14. Before contacting any attorney regarding this lawsuit or claim, had you ever seen any television or print advertisements regarding possible claims against inferior Vena Cava Filter manufacturers? Yes X _____ No _____

If Yes, set forth the approximate date and nature of any such advertisement, whether the advertisement included the name of a law firm, whether the advertisement specifically mentioned C. R. Bard, Inc., Bard Peripheral Vascular, Inc., or "Bard", and other details that you recall. Yes, latter part of 2015, but do not remember the name of the law firm or if Bard was mentioned. I do not remember if it mentioned Bard.

II. CLAIM INFORMATION

1. Have you ever received a Bard Inferior Vena Cava Filter? Yes ☐ No ☐

If Yes, please check the box(es) for each type of Bard Inferior Vena Cava Filter you have received:

☐ Recovery®

☐ G2®

☐ G2®X

☐ G2®Express

☐ Eclipse®

☐ Meridian®

☐ Denali®

☐ Simon Nitinol

☐ Other (please identify): _____

2. For each Bard Inferior Vena Cava Filter identified above, please provide the following information:

(a) The date each Bard Inferior Vena Cava Filter was implanted in you:

(b) The product code and lot number of each Bard Inferior Vena Cava Filter implanted in you:

(c) Current location of the Bard Inferior Vena Cava Filter, including any portion thereof, if known:

3. Describe your understanding of the medical condition for which you received the Bard Inferior Vena Cava Filter(s):

4. Give the name and address of the doctor who implanted the Bard Inferior Vena Cava Filter(s): _____

5. Give the name and address of the hospital or other healthcare facility where the Bard Inferior Vena Cava Filter was implanted: _____

6. Have you ever been implanted with any other vena cava filters or related product(s) besides the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar condition(s) identified in your response to question 3 above? Yes _____ No _____

If Yes:

(a) Please identify any such device(s) or product(s). _____

(b) When was this device or product implanted in you? _____

- (c) Did the implantation take place before, at the same time, or after the procedure during which you were implanted with a Bard Inferior Vena Cava Filter? _____
- (d) Who was the physician who implanted this other device or product? _____
- (e) At what hospital or facility was this other device or product implanted in you? _____
- (f) Why was this other device or product implanted in you? _____
7. Other than the Bard Inferior Vena Cava Filter device that is the subject of your lawsuit or identified in response to question 6 above, are you aware of any other Vena Cava Filter(s) implanted inside your body at any time? Yes ☐ No ☐
- If yes, please provide the following information:
- (a) Product name: _____
- (b) Date of procedure placing it and name and address of doctor who placed it: _____
- (c) Condition sought to be treated through placement of the device: _____
- (d) Any complications you encountered with the medical product or procedure: _____
- (e) Does that product remain implanted inside of you today? Yes _____ No _____
8. Prior to implantation with a Bard Inferior Vena Cava Filter, did you receive any written and/or verbal information or instructions regarding the Bard Inferior Vena Cava Filter, including any risks or complications that might be associated with the use of the same? Yes ☐ No ☐ Don't Know ☐

If Yes:

- (a) Provide the date you received the written and/or verbal information or instructions:

- (b) Identify by name and address the person(s) who provided the information and instructions:

- (c) What information or instructions did you receive?

- (d) If you have copies of the written information or instructions you received, please attach copies to your response.

- (e) Were you told of any potential complications from the implantation of the Bard Inferior Vena Cava Filter(s)? Yes ☐ No ☐ Don't Know ☐

- (f) If yes to (e), by whom?

- (g) If yes to (e), what potential complications were described to you?

9. Do you believe that the Bard Inferior Vena Cava Filter(s) remains implanted in you?

Yes ☐ No ☐ Don't Know ☐

If Yes:

- (a) Has any doctor recommended removal of the Bard Inferior Vena Cava Filter(s)?

Yes ☐ No ☐

If Yes:

(i) Identify by name and address every doctor who recommended removal of the Bard Inferior Vena Cava Filter(s): _____

(ii) For each doctor identified in response to question 8(a)(i) above, state your understanding of why the doctor recommended removal. _____

(iii) For each doctor identified in response to question 8(a)(i) above, state when the doctor recommended removal. _____

10. Has the Bard Inferior Vena Cava Filter(s) implanted in you been removed, in whole or in part?

Yes _____ No _____ Don't Know _____

If Yes:

(a) Where, when, and by whom was the Bard Inferior Vena Cava Filter(s), or any portion of it, removed? _____

(b) What portion of the Bard Inferior Vena Cava Filter(s) was removed on the date indicated in response to question 9(a) above? _____

(c) Please check all that apply regarding the removal procedure(s):

☐ Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Other, Describe: _____

☐ Unknown

(d) Does any portion of the Bard Inferior Vena Cava Filter(s) remain implanted in you? Yes _____ No _____ Don't Know _____
If Yes, explain what portion of the Bard Inferior Vena Cava Filter(s) you believe is still implanted in you: _____

(e) Explain why you consented to have the Bard Inferior Vena Cava Filter(s), or any portion thereof, removed?

(f) Does any medical provider, physician, entity, or anyone else acting on your behalf have possession of any portion of the Bard Inferior Vena Cava Filter that was previously implanted in you and subsequently removed?
Yes _____ No _____ Don't Know _____
If Yes, please state the name and address of the person or entity having possession of same. _____

11. Has any doctor or healthcare provider unsuccessfully attempted to remove the Bard Inferior Vena Cava Filter(s) implanted in you?

Yes [REDACTED] No [REDACTED] Don't Know [REDACTED]

If Yes:

(a) How many attempts have been made to remove the Bard Inferior Vena Cava Filter(s) implanted in you? [REDACTED]

(b) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter Removal/Attempted Removal #1

Doctor: [REDACTED]

Hospital/Medical Facility: [REDACTED]

Date: [REDACTED]

Filter Removal/Attempted Removal #2

Doctor: _____

Hospital/Medical Facility: _____

Date: _____


Filter Removal/Attempted Removal #3

Doctor: _____

Hospital/Medical Facility: _____

Date: _____

- (c) Please check all that apply regarding attempted removal procedure #1:

 Attempted but unsuccessful percutaneous removal procedure

Attempted but unsuccessful open abdominal procedure

Attempted but unsuccessful open chest procedure

Other, Describe: _____

Unknown

- (d) Please check all that apply regarding attempted removal procedure #2:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

☐ Unknown

- (e) Please check all that apply regarding attempted removal procedure #3:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

☐ Unknown

12. Do you claim that your Bard Inferior Vena Cava Filter(s) fractured?

Yes

No

If Yes:

(i) Please state the number of fractured struts retained in your body?

(ii) Please identify the location(s) within your body of each retained filter strut.

(iii) Please provide the date or approximate date when you were first informed of each fractured strut.

(iv) Has any health care provider recommended to you that a retained filter strut(s) should be removed?

Yes _____ No _____

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

(v) Has any health care provider recommended to you that a retained filter strut should not be removed?

Yes _____ No _____

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

- (vi) Have any fractured struts been removed, or attempted to have been removed, from your body?

Yes _____ No _____

If Yes:

- (1) If any fractured filter strut has been removed (or a doctor has attempted to remove any strut), please check all that apply regarding the removal/attempted removal procedure(s):
- ☐ Removed percutaneously
 - ☐ Removed via an open abdominal procedure
 - ☐ Removed via an open chest procedure
 - ☐ Attempted but unsuccessful percutaneous removal procedure
 - ☐ Attempted but unsuccessful open abdominal procedure
 - ☐ Attempted but unsuccessful open chest procedure
 - ☐ Other, Describe: _____
 - ☐ Unknown
- (2) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).
- Filter Strut Removal/Attempted Removal #1
- Doctor: _____
- Hospital/Medical Facility: _____
- Date: _____
- Filter Strut Removal/Attempted Removal #2
- Doctor: _____
- Hospital/Medical Facility: _____
- Date: _____

13. Do you claim that you suffered bodily injuries as a result of the implantation of the Bard Inferior Vena Cava Filter(s)? Yes ☐ No ☐

If Yes:

- (a) Describe the bodily injuries, including any emotional or psychological injuries that you claim resulted from the implantation, attempted removal and/or removal of the Bard Inferior Vena Cava Filter(s)? ☐

[REDACTED]

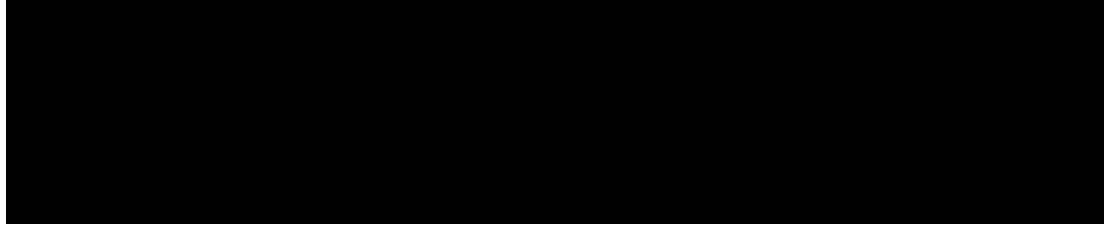
- (b) When was the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the Bard Inferior Vena Cava Filter(s)?

[REDACTED]

- (c) When did you first attribute these bodily injuries to the Bard Inferior Vena Cava Filter(s)? ☐

[REDACTED]

- (d) To the best of your knowledge and recollection, please state the approximate date when you first saw a health care provider for any of the bodily injuries, or symptoms related thereto, you claim to have experienced related to the Bard Inferior Vena Cava Filter(s)?



- (e) To the best of your knowledge and recollection, has any health care provider ever told you orally or in writing that any symptoms related to bodily injury are related to the Bard Inferior Vena Cava Filter(s)?

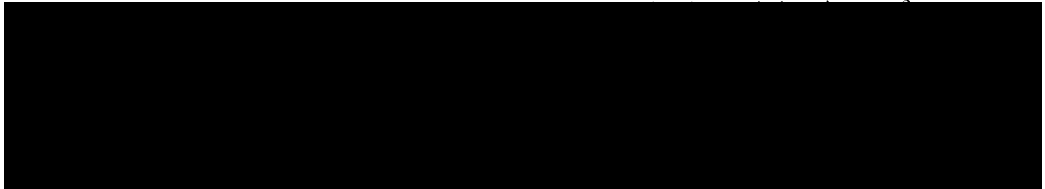
Yes ☐ No ☐

If Yes, please state the name and address of any such health care provider, as well as providing the approximate date the statement was made, and provide the details of the communication: _____

- (f) Are you currently experiencing symptoms related to your claimed bodily injuries?

Yes ☐ No ☐

If Yes, please describe your symptoms in detail:



- (g) Are you currently seeing, or have you ever seen, a doctor or healthcare provider for any of the bodily injuries or symptoms listed above?

Yes ☐ No ☐

If Yes, please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

Provider Name and Address	Condition Treated	Approximate Dates of Treatment

--	--	--

h) Were you hospitalized at any time for the bodily injuries you listed above?

Yes ☐ No ☐

If Yes, please provide the following:

Hospital Name and Address	Condition Treated	Approximate Dates of Treatment

14. Are you making a claim for lost wages or lost earning capacity?

Yes _____ No X

(a) If yes, state the annual gross income derived from your employment for each year, beginning five (5) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) until the present: _____

(b) If yes, for what period of time are you claiming lost wages? _____

(c) If you are claiming lost earning capacity, do you claim that you have a claim for future lost wages?

Yes _____ No _____

If yes, for what period of time do you claim you have lost future wages?

15. Are you making a claim for lost out-of-pocket expenses? Yes X No _____

If yes, please identify and itemize all out-of-pocket expenses you have incurred.

Past medical bills and expenses, future medical care and expenses including without limitation removal surgery (or surgeries) and medical monitoring, and any other damages revealed during discovery.

16. Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the Bard Inferior Vena Cava Filter(s)?

Yes _____ No X

If yes, identify by name and address the person who filed the loss of consortium claim ("Consortium Plaintiff") and state the relationship of that person to you and state the specific nature of the Consortium Plaintiff's claim. _____

17. Please indicate whether the Consortium Plaintiff alleges any of the damages set forth below: Not Applicable

Claims	Yes/No
Loss of services of spouse	
Impaired sexual relations	
Lost wages/lost earning capacity	
Lost out-of-pocket expenses	
Physical injuries	
Psychological injuries/emotional injuries	
Other	

18. Please list the name and address of any healthcare providers the Consortium Plaintiff has sought treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to his/her claim. Not applicable
- _____
- _____
- _____

19. Have you or anyone acting on your behalf had any communication, oral or written, with any of the Bard Defendants and/or their representatives?

Yes _____ No X _____ Don't Know _____

If yes, set forth: (a) the date of any communication, (b) the method of communication, (c) the name of the person with whom you communicated, and (d) the substance of the communications. _____

III. MEDICAL BACKGROUND

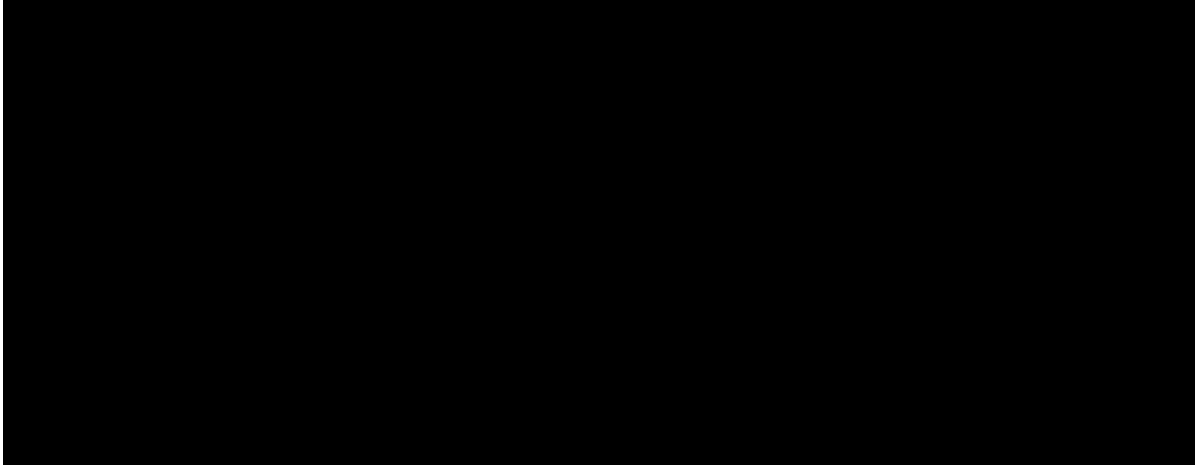
1. Provide your current: Age Height Weight
2. Provide your: Age Weight (approximate, if unknown) at the time the Bard Inferior Vena Cava Filter was implanted in you.
3. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had in the ten (10) year period BEFORE implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

Approximate Date	Description of Surgery or Hospitalization	Doctor or Healthcare Provider Involved (including address)

[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations leading up to the implantation of the Bard Inferior Vena Cava Filter.]


4. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had AFTER implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

Approximate Date	Description of Surgery or Hospitalization	Doctor or Healthcare Provider Involved (including address)
------------------	---	--



[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations after the implantation of the Bard Inferior Vena Cava Filter.]

5. To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital or other health care provider from which you have received medical advice and/or treatment from ten (10) years before the date the filter was implanted to the present:

Name and Specialty	Address	Approximate Date/Years of Visits
		

6. *Before the implantation* of the Bard Inferior Vena Cava Filter(s), did you regularly exercise or participate in activities that required lifting or strenuous physical activity? (Please include all physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

Yes _____ No x

If yes, please describe each activity in detail. _____

7. *Since the implantation* of the Bard Inferior Vena Cava Filter(s), have you regularly exercised or participated in activities that required lifting or strenuous physical activity? (Please describe all range of physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

Yes X No _____

If yes, please describe each activity in detail. _____

Walking, household chores

8. During the past ten (10) years, what have been your primary hobbies or recreational activities? _____

Cake Making/Decorating, reading, TV, crafts, coloring, playing with my grandchildren, outdoor concerts and festivals

- (a) Do you claim that you are unable to participate in any of the hobbies or recreational activities listed in response to question 8 above as a result of you having been implanted with a Bard Inferior Vena Cava Filter(s)?

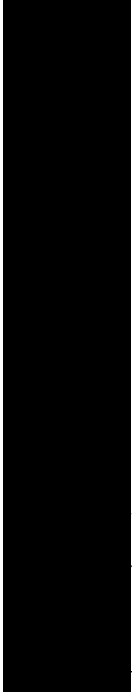
Yes _____ No X

- (b) If yes, what hobbies or recreational activities do you claim that you are unable to participate in as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)? _____

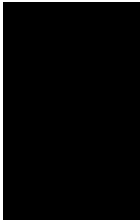
- (c) For what period of time do you claim that you were or have been unable to participate in any hobbies or recreational activities as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)?

N/A

9. To the best of your knowledge, have you ever been told by a doctor or another health care provider that you have suffered, may have suffered, or presently do suffer from any of the following:

 Lupus
Crohn's Disease
Factor V Leiden
Protein Deficiency
Spinal Fusion or Other Back Procedures
Anti-thrombin Deficiency
Prothrombin Mutation
Deep Vein Thrombosis
Pulmonary Embolism
Auto Immune Disorder
Varicose Veins
Heart Procedures
Blood Disorder

Please Describe: _____

 Bariatric Surgery
Anticoagulation Medication (e.g., Coumadin, Warfarin, etc.)
Ulcerative Colitis/Inflammatory Bowel Disease (IBD)
Cancer

Please Describe: _____

* * * * *

THE FOLLOWING QUESTIONS ARE CONFIDENTIAL AND SUBJECT TO THE PROTECTIVE ORDER APPLICABLE TO THIS CASE.

- (A) Have you been diagnosed with and/or treated for any drug, alcohol, chemical and/or other addiction or dependency during the five (5) years prior to the filing of this lawsuit through the present? Yes ☐ No ☐
If yes, specify type and time period of dependency, type of treatment received, name of treatment provider, and current status of condition:

- (B) Have you experienced, been diagnosed with or received psychiatric or psychological treatment of any type, including therapy, for any mental health conditions including depression, anxiety, or other emotional or psychiatric disorders during the five (5) years prior to the filing of this lawsuit through the present? Yes ☐ No ☐
If yes, specify condition, date of onset, medication/treatment, treating physician and current status of condition:

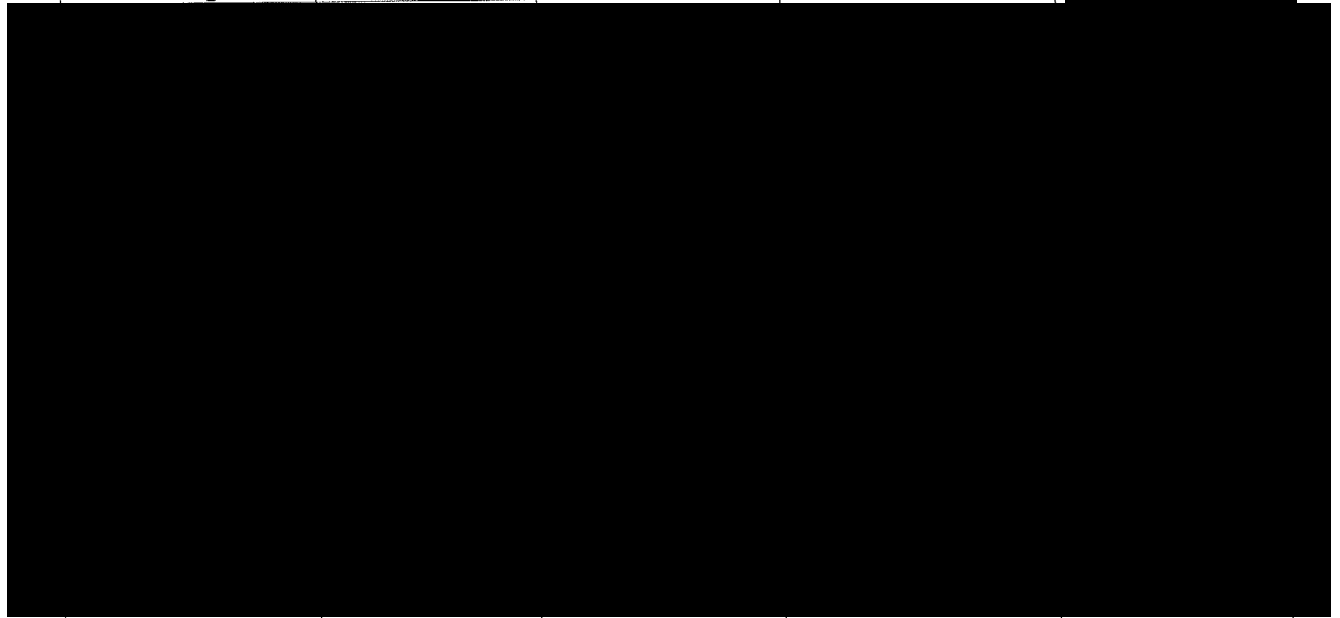
* * * * *

10. Do you now or have you ever smoked tobacco products? Yes X No
If yes:

How long have/did you smoke? 10 years, quit for a year, 3 years


11. List each prescription medication you have taken for more than three (3) months at a time during the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present, giving the name and address of the pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

Medication and Dosage	Prescribing Physician	Pharmacy Name and Address	Reason for Taking Medication	Approximate Date(s) of Use
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IV. INSURANCE INFORMATION

1. Provide the following information for any past or present medical insurance coverage from the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present:

Insurance Company Name and Address	Policy Number	Name of Policy Holder/Insured (if different than yourself)	Approximate Dates of Coverage
			

2. To the best of your knowledge, have you ever been approved to receive or are you currently receiving Medicare/Medicaid benefits due to age, disability, condition, or any other reason or basis?

Yes X No

If yes, please specify the date on which you first became eligible: 2011

[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]

V. PRIOR CLAIM INFORMATION

1. Have you filed a lawsuit or made a claim in the last ten (10) years, other than in the present suit relating to any bodily injury?

Yes _____ No X

If yes, please specify the following:

- (a) Court in which the lawsuit/claim was filed or initiated: _____

- (b) Case/Claim Number: _____
- (c) Nature of Claim/Injury: _____

2. Have you ever applied for Workers' Compensation (WC), Social Security disability (SSI or SSD) benefits, or other State or Federal disability benefits?

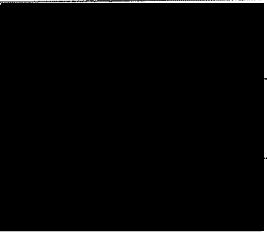
Yes X No _____

If yes, please specify the following:

- (a) Date (or year) of application: 2009 or 2010
- (b) Type of benefits sought: SSD
- (c) Agency/Insurer from which you sought the benefits: SSA
- (d) Nature of the claimed injury/disability: Depression, weight, back injury
- (e) Whether the claim was accepted or denied: Accepted

VI. FACT WITNESSES

1. Identify by name, address, and relationship to you, all persons (other than your healthcare providers) who possess information concerning your injuries and/or current medical condition:

Name	Address	Relationship to You	Information You Believe Person Possesses
Angelic Thompson	Fort Gay, WV	Daughter	
Lorelei Thompson	West Van Lear, KY	Daughter	
Joshua Thompson	Fort Gay, WV	Son	

VII. IDENTIFICATION OF DOCUMENTS AND OTHER ELECTRONICALLY STORED INFORMATION

For the period beginning three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter until the present, please identify all research, including on-line research, that you conducted regarding the medical complaints or condition for which you received the Bard Inferior Vena Cava Filter (pulmonary thromboembolism, anticoagulant therapy, etc.) Identify the date, time, and source, including any websites visited. (Research conducted subsequent to and for the purpose of understanding the legal and strategic advice of your counsel is not considered responsive to this request.)

N/A

VIII. DOCUMENT REQUESTS

1. RELEASES.

NOTE: Please sign and attach to this Fact Sheet the authorizations for the release of records appended hereto.

2. DOCUMENTS. State whether you have any of the following documents in your possession, custody, and/or control. If you do, please provide a true and correct copy of any such documents with this completed Fact Sheet. Please ensure that the production of documentation includes specific reference to the questions to which the document is provided in response, and please identify any documents you are producing responsive to a question with Bates Stamp identifiers.

(a) If you were appointed by a Court to represent the plaintiff in this lawsuit, produce any documents demonstrating such appointment.

(i) Not applicable X

(ii) The documents are attached [OR] I have no documents

(b) If you represent the Estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).

(i) Not applicable X

(ii) The documents are attached [OR] I have no documents

(c) Produce each and every medical record of each and every medical facility, pharmacy, or practitioner of the healing arts identified by you in response to the questions in Sections II and III above regarding your medical care and history for the time period beginning ten (10) years prior to the implantation of the Bard Inferior Vena Cava Filter and continuing to the present.

(i) Not applicable

Records requested but not received. They will be provided when received.

(ii) The documents are attached: [OR] I have no documents X

(d) Produce any communication (sent or received) in your possession, which shall include materials accessible to you from any computer on which you have sent or received such communications, concerning the Bard Inferior Vena Cava Filter(s) or subject of this litigation, including, but not limited to all letters, emails, blogs, Facebook posts, Tweets, newsletters, etc. sent or received by you. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)

(i) Not applicable X

(ii) The documents are attached [OR] I have no documents

- (e) Produce all documents, including journal entries, lists, memoranda, notes, diaries, photographs, video, DVDs or other media, discussing or referencing the Bard Inferior Vena Cava Filter(s), the injuries and/or damages you claim resulted from the Bard Inferior Vena Cava Filter(s), and/or evidencing your physical condition from three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) to present. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)
- (i) Not applicable X
- (ii) The documents are attached [OR] I have no documents
- (f) Produce any Bard Inferior Vena Cava Filter product packaging, labeling, advertising, or any other product-related items in your possession, custody or control.
- (i) Not applicable
- (ii) The documents are attached X [OR] I have no documents
- (g) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) and the Food and Drug Administration (FDA), or between you and any employee or agent of the Bard Defendants, regarding Bard Inferior Vena Cava Filters.
- (i) Not applicable X
- (ii) The documents are attached [OR] I have no documents
- (h) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to the Food and Drug Administration (FDA) and/or the Department of Health and Human Services regarding Bard Inferior Vena Cava Filters.
- (i) Not applicable X
- (ii) The documents are attached [OR] I have no documents
- (i) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) with anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

- (i) Not applicable X
- (ii) The documents are attached [OR] I have no documents
- (j) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.
- (i) Not applicable X
- (ii) The documents are attached [OR] I have no documents
- (k) Produce all documents in your possession, custody, or control evidencing or relating to any correspondence or communication between C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. (or any related companies or divisions) and any of your doctors, healthcare providers, and/or you relating to Bard Inferior Vena Cava Filters, except as to those communications which are protected by the attorney-client privilege or attorney work product doctrine.
- (i) Not applicable X
- (ii) The documents are attached [OR] I have no documents
- (l) Produce all documents in your possession, custody, or control reflecting, describing, or in any way relating to any instructions or warnings you received prior to implantation of any Inferior Vena Cava Filter(s) concerning the risks and/or benefits associated with Inferior Vena Cava Filter(s), including but not limited to the Bard Inferior Vena Cava Filter implanted in you.
- (i) Not applicable
- (ii) The documents are attached [OR] I have no documents X
- (m) Produce any and all documents reflecting the model number and lot number of the Bard Inferior Vena Cava Filter(s) you received.
- (i) Not applicable
- (ii) The documents are attached X [OR] I have no documents
- (n) If you underwent surgery or any other procedure to remove, in whole or in part, the Bard Inferior Vena Cava Filter(s), produce any and all documents, other than documents that may have been generated by expert witnesses retained by your

counsel for litigation purposes, that relate to any evaluation of the Bard Inferior Vena Cava Filter(s) removed from you.

- (i) Not applicable_____
- (ii) The documents are attached X [OR] I have no documents_____
- (o) If you claim lost wages or lost earning capacity, produce copies of your Federal and State tax returns for the five (5) years prior to implantation of the Bard Inferior Vena Cava Filter(s) to the present redacting irrelevant information.
 - (i) Not applicable X
 - (ii) The documents are attached_____ [OR] I have no documents_____
- (p) Produce all documents in your possession, custody, or control concerning payment by Medicare on behalf of the injured party and relating to the injuries claimed in this lawsuit. This includes, but is not limited to Interim Conditional Payment summaries and/or estimates prepared by Medicare or its representatives regarding payments made on your behalf for medical expenses relating to the subject of this litigation.
 - (i) Not applicable_____


Medical bills have been requested and will be provided.

- (ii) The documents are attached_____ [OR] I have no documents X

[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]

- (q) Produce all screenshots of all webpages of each type of social media used by you (including, but not limited to, Facebook, Twitter, Instagram, Vine, Snapchat, YouTube, LinkedIn) showing any and all “posts” and/or “messages” from the date of implantation to the present.
 - (i) Not applicable X
 - (ii) The documents are attached_____ [OR] I have no documents_____
- (r) Produce the Bard Inferior Vena Cava Filter(s) or any and all components thereof previously implanted in you.
Not Applicable

VERIFICATION

I, , declare under penalty of perjury, subject to all applicable laws and in the presence of the below named witness, that I have carefully reviewed the final copy of this Plaintiff Fact Sheet dated 7-21-16 and verified that all of the information provided is true and correct to the best of my knowledge, information and belief.

Deanna Porter

Signature of Witness

Deanna Porter

Name of Witness

